IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF FLORIDA
TALLAHASEE DIVISION

BIG BEND COMMUNITY BASED CARE, INC., LUTHERAN SERVICES FLORIDA, INC., CENTRAL FLORIDA CARES HEALTH SYSTEM, INC., SOUTHEAST FLORIDA BEHAVIORAL HEALTH NETWORK, INC., and CENTRAL FLORIDA BEHAVIORAL HEALTH NETWORK, INC.

Plaintiff,

v.

PURDUE PHARMA, L.P., PURDUE PHARMA, INC., THE PURDUE FREDERICK COMPANY, ENDO PHARMACEUTICALS, INC., ENDO HEALTH SOLUTIONS INC., JANSSEN PHARMACEUTICALS, INC., JOHNSON & JOHNSON, CEPHALON, INC., TEVA PHARMACEUTICAL INDUSTRIES, LTD., TEVA PHARMACEUTICAL USA, INC., ALLERGAN PLC, WATSON LABORATORIES, INC., ACTAVIS PHARMA, INC., ACTAVIS LLC, ACTAVIS PLC, ACTAVIS, INC., WATSON PHARMACEUTICALS, INC., WATSON PHARMA, INC., AND WATSON LABORATORIES, INC., MALLINCKRODT, PLC AND MALLINCKRODT, LLC, INSYS THERAPUETICS, INC., MCKESSON CORPORATION, AND CARDINAL HEALTH, INC.; and JOHN AND JANE DOES 1 THROUGH 100, INCLUSIVE,

Defendants.

Case No. 4:18-cv-00183

COMPLAINT AND
DEMAND FOR JURY TRIAL

I. INTRODUCTION

1. Big Bend Community Based Care, Inc. Lutheran Services Florida, Inc. Central Florida Cares Health System, Inc., Southeast Florida Behavioral Health Network, Inc., and Central Florida Behavioral Health Network, Inc. (the "BHME's") bring this action pursuant to their statutory and common law authority to redress Purdue Pharma, L.P., Purdue Pharma, Inc., The Purdue Frederick Company, Endo Pharmaceuticals, Inc., Endo Health Solutions Inc., Janssen Pharmaceuticals, Inc., Johnson & Johnson, Cephalon, Inc., Teva Pharmaceutical Industries, Ltd., Teva Pharmaceutical USA, INC., Allergan PLC, Watson Laboratories, Inc., Actavis Pharma, Inc., Actavis LLC, Actavis Pharma, Inc., Watson Pharmaceuticals, Inc., Watson Pharma, Inc., and Watson Laboratories, Inc., Mallinckrodt, PLC and Mallinckrodt, LLC, Insys Therapeutics, Inc., McKesson Corporation, and Cardinal Health, Inc. (together, "Defendants") campaign of unfairly and deceptively marketing and falsely advertising opioids, for creating a public nuisance, for fraud, and for violations the Racketeer Influenced and Corrupt Organizations Act ("RICO"), 18 U.S.C. § 1961, *et seq*.

2. Defendants, drug manufacturers and distributors of opioids, represented to physicians and the public that opioids were safe and effectively treated pain, with a low risk for addiction. But for many of those prescribed opioids, the consequences have been severe. Every day, people are admitted to emergency rooms across the country because of opioid-related abuse. Naloxone, a costly medication used to block and reverse the effects of an opioid overdose, is now routinely carried by law enforcement and EMTs. Making matters worse, individuals addicted to opioids by virtue of the conduct of Defendants and left without a prescription or the resources to obtain them, often turn to heroin, leading to another crisis directly related to the distribution of opioids.

3. This opioid crisis is the direct result of a sophisticated and well-developed marketing scheme by Defendants to sell and distribute drugs that have little or no demonstrated efficacy for the pain they are purported to treat. Despite minimal scientific evidence indicating that opioids offer any long-term benefit in treating chronic pain, Defendants misleadingly advertised their opioids as a cure-all and pushed hundreds of millions of pills into the marketplace for consumption, fueling a crisis of unprecedented levels.

4. In fact, to date, there have been no long-term studies that demonstrate that opioids are effective for treating long-term or chronic pain. Instead, reliable sources of information, including from the CDC last year, indicate that there is *"[n]o evidence*" to show "a long-term benefit of opioids in pain and function versus no opioids for chronic pain."[1]

5. What is more, significant research has demonstrated the colossal dangers of opioids. The CDC, for example, concluded that "[e]xtensive evidence shows the possible harms of opioids (including opioid use disorder, overdose, and motor vehicle injury)" and that "[o]pioid pain medication use presents serious risks, including overdose and opioid use disorder."[2]

6. This crisis arose because Defendants told physicians and the public, through a well-orchestrated marketing campaign, that the risk of addiction to prescription opioids was low when opioids were prescribed to treat chronic pain. In support of this claim, Defendants misrepresented research and manipulated data to make opioids appear safer than they are. For example, Defendants widely cited a one-paragraph letter-to-the-editor published in the New England Journal of Medicine ("NEJM") declaring that the incidence of opioid addiction was "rare."[3]

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[1] Deborah Dowell, M.D., Tamara M. Haegerich, Ph.D., and Roger Chou, M.D., *CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016*, Centers for Disease Control and Prevention (Mar. 18, 2016), https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm.

[2] *Id.*

[3] Jane Porter and Herschel Jick, MD, *Addiction Rare in Patients Treated with Narcotics*, 302(2) N. Engl. J. Med. 123 (Jan. 10, 1980), http://www.nejm.org/doi/pdf/10.1056/NEJM198001103020221.

7. Defendants used this letter to heavily promote opioids as a safe form of treatment for chronic pain, despite that fact that the letter's authors studied only the files of patients administered opioids to treat acute pain in a hospital under physician supervision.[4] Indeed, notwithstanding the very limited scope of the study, Defendants regularly utilized and cited the letter as proof of the low addiction risk in connection with taking opioids.

8. Defendants' opioid marketing campaign has been wildly successful and profitable. Their reliance on this letter and other sources of information that were false and misleading (as described in more detail below) ultimately resulted in a well-documented and substantial increase in the prescription of opioids.

9. But on June 1, 2017, the NEJM published another letter calling attention to the way the one-paragraph 1980 letter had been "grossly misrepresented" and irresponsibly cited. In particular, the letter explained:

> [W]e found that a five-sentence letter published in the Journal in 1980 was heavily and uncritically cited as evidence that addiction was rare with long-term opioid therapy. We believe that this citation pattern contributed to the North American opioid crisis by helping to shape a narrative that allayed prescribers' concerns about the risk of addiction associated with long-term opioid therapy. [5]

In short, Defendants successfully manipulated the 1980 letter-to-the-editor as the "evidence" supporting their fundamental misrepresentation that the risk of opioid addiction was low when opioids were prescribed to treat pain.

10. References to the 1980 letter-to-the-editor are just one example of the false and misleading statements made by Defendants over the last 20 years, including statements that continue to this day, regarding the purported benefits and minimal risks of opioids.

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[4] *Id.*

[5] Pamela T.M. Leung, B.Sc. Pharm., Erin M. Macdonald, M.Sc., Matthew B. Stanbrook, M.D., Ph.D., Irfan Al Dhalla, M.D., David N. Juurlink, M.D., Ph.D., *A 1980 Letter on the Risk of Opioid Addiction*, 376 N. Engl. J. Med. 2194-95 (June 1, 2017), http://www.nejm.org/doi/full/10.1056/NEJMc1700150#t=article.

11. Defendants spent vast sums of money promoting and marketing opioids to doctors, patients, and the public, including through direct marketing, front groups, key opinion leaders, medical journals, and unbranded advertising. Through their well-orchestrated campaign, Defendants were able to convey a message that touted the purported benefits of opioids to treat pain and downplayed the substantial risks of addiction related to opioid use.

12. Defendants consistently, deliberately, and recklessly made false and misleading statements—including to doctors and patients—regarding, *inter alia*, the low risk of addiction to opioids, the need to prescribe more opioids to treat pain, risk-mitigation strategies to safely prescribe opioids, the lack of risk associated with higher dosages of opioids, the benefits of abuse-deterrent technology to curb abuse, and that long-term opioid use improved patients' function and quality of life.

13. Defendants profited enormously from this campaign, generating billions of dollars in sales. Annual prescription opioid sales have consistently approached more than $10 billion in recent years. Indeed, despite making up only 4.6% of the world's population, Americans consume 80% of the world's opioid supply, and 99% percent of the global hydrocodone supply.

14. In short, Defendants made and continue to make false and misleading statements about the benefits and risks of opioids, and did so through a well-funded marketing and advertising scheme to doctors, patients, and the public—including to doctors and patients in The BHME's—despite knowing that there was little to no evidence to support their claims. As a result of these false and misleading statements, The BHME's have suffered significant economic damages, including but not limited to increased health services costs, and costs related to responding to and dealing with opioid-related crimes and emergencies.

15. In addition to the manufacturers, opioid distributors are also responsible for the opioid crisis by virtue of their unique role in the distribution chain and their commensurate legal obligation to monitor, control, and stop abuse.

16. Substantially all prescribed opioids *must* flow through the wholesale drug distributors because federal law requires that opioids be distributed through a closed system. Accordingly, the distributors are legally required to spot and report red flags in the distribution chain.

17. McKesson, Cardinal and their fellow distributors admit that they are the gatekeepers – the watch dogs – for preventing opioid abuse, stating in their self-created Industry Compliance Guidelines: "***distributors are uniquely situated to perform due diligence in order to help support the security of the controlled substances . . . and reduce the possibility that controlled substances within the supply chain will reach locations they are not intended to reach***."[6]

18. The Department of Justice and the DEA have investigated, initiated, and settled actions against both McKesson and Cardinal Health on multiple occasions for failures to maintain adequate controls over prescription opioids, as required by federal law. Both companies paid substantial fines because multiple facilities under their control continued to ship massive quantities of prescription opioids after it should have been clear to them that the orders were suspicious or illegitimate.

19. By way of example McKesson Corp. deliberately failed to detect and report "suspicious" orders of opioids, despite being required to do so. McKesson was fined a record

[6] *See* Healthcare Distribution Management Association (HDMA) Industry Compliance Guidelines: Reporting Suspicious Orders and Preventing Diversion of Controlled Substances ("Industry Compliance Guidelines" or "Guidelines").

$150 million by the federal government for its blatant failure to report suspicious orders in violation of federal law.

20. Similarly, Cardinal Health was fined $44 million for its failure to report suspicious narcotic orders to the Drug Enforcement Agency ("DEA").

21. Unfortunately, the distributors wholly ignored their admitted legal obligations. Instead of implementing controls to stop opioid abuse and alerting authorities to suspicious orders, the distributors have chosen to abuse their privileged position, lining their pockets by shipping massive quantities of drugs to pharmacies and dispensaries without performing any checks – with devastating consequences to the BHME's and the patients they serve.

22. Accordingly, the BHME's brings this action to hold Defendants liable for their deliberate misrepresentation regarding the benefits and risks of using opioids to treat pain—conduct that (i) violates the Florida's Deceptive and Unfair Trade Practices Act, Fla. Stat. § 501.201, et seq. (ii) constitutes a public nuisance under Floirda law, (iii) constitutes negligence under Florida law, and (iv) violates the Racketeer Influenced and Corrupt Organizations Act ("RICO), 18 U.S.C. § 1961, *et seq*.

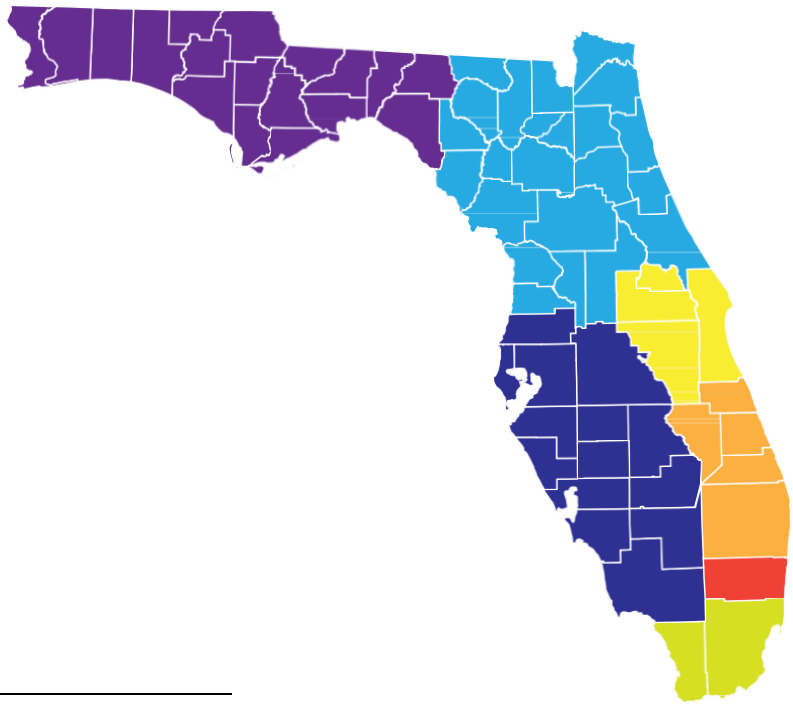
II. PARTIES

A. Plaintiffs

23. A Behavioral Health Managing Entity is a nonprofit organization that, pursuant to Florida statute,[7] is responsible for delivering behavioral health services, including substance abuse and mental health services, to uninsured Floridians.[8] The services the BHME's provide are vital to the most vulnerable Floridians.[9]

24. The Florida Department of Children and Families has divided the state into seven geographic regions and contracts with one BHME per region, with each BHME being the primary provider of publicly funded behavioral health services to the uninsured for the counties in its regions.[10]

25. The seven regions are reflected in the graphic below:



[7] Florida's BHME's exist to "plan, coordinate, and contract for the delivery of community health and substance abuse services, to improve access to care, to promote service continuity, to purchase services, and to support efficient delivery of services." Fla. Stat. § 394.9082(1)(a); *see also "Managing Entities: Presentation to the Senate Children Families and Elder Affairs Committee*," Florida Council for Community Mental Health (FCCMH).
[8] http://floridataxwatch.org/resources/pdf/ManagingEntitiesFINAL.pdf
[9] *Id.*
[10] *Id.*

26. Each BHME has its own established and contracted network of community mental health and substance abuse providers.[11]

27. BHMEs offer a vehicle for the provision of the full range of needs for uninsured adults and children with complex behavioral health issues, including opioid addiction, and provide oversight for the quality and consistency of providers.[12]

28. BHMEs also perform several of the administrative functions previously performed by the Florida Department of Children and Families, such as negotiating, managing, and, importantly, ***paying*** for contracts with local providers.[13] In addition, BHMEs have taken on many essential tasks not previously executed by the Department of Children and Families, such as credentialing providers, creating provider networks, and performing provider reviews to assess the quality of the services provided.[14]

29. The statute that authorizes the existence of BHME's also bestows on BHME's broad statutory authority to take the necessary actions to fulfill their purposes and serve their communities. For example, BHME's have the authority to:

- Expand the scope of services as necessary to meet the behavioral needs of the Floridians it serves[15];
- Take steps necessary to promote the development of a coordinated system of care[16];
- Support care coordination activities that improve outcomes among priority populations[17];

[11] "Care Management Entities: A Primer." Center for Health Care Strategies, Inc. (2011).
[12] http://floridataxwatch.org/resources/pdf/ManagingEntitiesFINAL.pdf
[13] "DCF Behavioral Health Contracting and Reimbursement: Current State Policy, Impact in Communities." (April 2006). Florida Alcohol and Drug Abuse Association (FADAA), *available at* http://www.fadaa.org/provider_networks.php
[14] http://floridataxwatch.org/resources/pdf/ManagingEntitiesFINAL.pdf.
[15] Fla. Stat. § 394.9082(5)(c).
[16] Fla. Stat. §394.9082(5)(d).
[17] Fla. Stat. §394.9082(5)(g).

- Pursue payments from third parties, including **employing "any…method needed to ensure that services are available and accessible."**[18]

30. The BHME's are legally and contractually responsible for ensuring that their contractors are compensated for the work they do and are also statutorily and contractually responsible for meeting the behavioral health and addiction needs of the communities they serve. Defendants' conduct has impaired and continues to impair the BHME's ability fulfill their statutory and contractual obligations causing both their contractors and their patients to suffer.

31. Plaintiff Big Bend Community Based Care, Inc. is a Florida non-profit corporation and BHME with a principal address of 525 MLK Jr. Boulevard, Tallahassee, Florida, 32301. Big Bend Community Based Care has the exclusive contract with the Florida Department of Children and Families to provide behavioral health services, including addressing and treating opioid addiction and related issues, in the following counties:

- Bay
- Calhoun
- Escambia
- Franklin
- Gadsden
- Holmes
- Jackson
- Jefferson
- Leon
- Liberty
- Madison
- Okaloosa
- Santa Rosa
- Taylor
- Wakulla
- Walton
- Washington

[18] Fla. Stat. §394.9082(5)(i) (emphasis added).

32. Plaintiff Lutheran Services, Inc. is a Florida non-profit corporation and BHME with a principal address of 3627 West Waters Avenue, Tampa, Florida 33614. Lutheran Services has the exclusive contract with the Florida Department of Children and Families to provide behavioral health services, including addressing and treating opioid addiction and related issues, in the following counties:

- Alachua
- Baker
- Bradford
- Citrus
- Clay
- Columbia
- Dixie
- Duval
- Flagler
- Gilchrist
- Hamilton
- Hernando
- Lafayette
- Lake
- Levy
- Marion
- Nassau
- Putnam
- St. Johns
- Sumter
- Suwanee
- Union
- Volusia

33. Plaintiff Central Florida Cares Health System, Inc. is a Florida non-profit corporation and BHME with a principal address of 707 Mendham Boulevard, Suite 201, Orlando, Florida 32825. Central Florida Cares Health System, Inc. has the exclusive contract with the Florida Department of Children and Families to provide behavioral health services, including addressing and treating opioid addiction and related issues, in the following counties:

- Brevard

- Orange
- Osceola
- Seminole

34. Plaintiff Central Florida Behavioral Health Network, Inc. is a Florida non-profit corporation and BHME with a principal address of 3627 West Waters Avenue, Tampa, Florida 33614. Central Florida Behavioral Health Network, Inc. has the exclusive contract with the Florida Department of Children and Families to provide behavioral health services, including addressing and treating opioid addiction and related issues, in the following counties:

- Charlotte
- Collier
- Desoto
- Glades
- Hardee
- Hendry
- Hillsborough
- Lee
- Manatee
- Pasco
- Pinellas
- Polk
- Sarasota

35. Plaintiff Southeast Florida Behavioral Health Network, Inc. is a Florida non-profit corporation and BHME with a principal address of 140 Intracoastal Pointe Drive, Suite 211, Jupiter, Florida 33477. Southeast Florida Behavioral Health Network, Inc. has the exclusive contract with the Florida Department of Children and Families to provide behavioral health services, including addressing and treating opioid addiction and related issues, in the following counties:

- Indian River
- Martin
- Okeechobee
- Palm Beach
- St. Lucie

B. Defendants

a. Manufacturer Defendants

36. At all relevant times, the Manufacturer Defendants (defined below) have packaged, distributed, supplied, sold, placed into the stream of commerce, labeled, described, marketed, advertised, promoted and purported to warn or purported to inform prescribers and users regarding the benefits and risks associated with the use of the prescription opioid drugs. The Manufacturer Defendants, at all times, have manufactured and sold prescription opioids without fulfilling their legal duty to prevent diversion and report suspicious orders.

37. Defendant Purdue Pharma, L.P. is a limited partnership organized under the laws of Delaware. Defendant Purdue Pharma, Inc. is a New York corporation with its principal place of business in Stamford, Connecticut. Defendant The Purdue Frederick Company is a Delaware corporation with its principle place of business in Stamford, Connecticut. Collectively, these entities are referred to as "Purdue."

38. Each Purdue entity acted in concert with one another and acted as agents and/or principals of one another in connection with the conduct described herein.

39. Purdue manufactures, promotes, sells, markets, and / or distributes opioids such as OxyContin, MS Contin, Dilaudid/Dilaudid HP, Butrans, Hysingla ER, and Targiniq ER in the United States, including Florida.

40. OxyContin, Butrans, and Hysingla ER are Schedule II and III opioids first approved in 1995, 2010, and 2014, respectively.

41. Purdue generates substantial sales revenue from its opioids. For example, OxyContin is Purdue's best-selling opioid, and since 2009, Purdue has generated between $2 and

$3 billion annually in sales of OxyContin, one of the primary prescription opioids available in the painkiller market.

42. Defendant Endo Pharmaceuticals, Inc. is a wholly owned subsidiary of Defendant Endo Health Solutions Inc. Both are Delaware corporations with their principal place of business in Malvern, Pennsylvania. Collectively, these entities are referred to as "Endo."

43. Each Endo entity acted in concert with one another and acted as agents and/or principals of one another in connection with the conduct described herein.

44. Endo manufacturers, promotes, sells, markets, and / or distributes opioids such as Percocet, Opana, and Opana ER in the United States, including in Florida.

45. Opana and Opana ER are Schedule II opioids first approved in 2006.

46. Defendant Janssen Pharmaceuticals, Inc. is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey, and is a wholly owned subsidiary of Defendant Johnson & Johnson, a New Jersey corporation with its principal place of business in New Brunswick, New Jersey. Collectively, these entities are referred to as "Janssen."

47. Both entities above acted in concert with one another and acted as agents and/or principals of one another in connection with the conduct described herein.

48. Johnson & Johnson is the only company that owns more than 10% of Janssen Pharmaceuticals, Inc., and corresponds with the FDA regarding the drugs manufactured by Janssen Pharmaceuticals, Inc. Johnson & Johnson also paid prescribers to speak about opioids manufactured by Janssen Pharmaceuticals, Inc. In short, Johnson & Johnson controls the sale and development of the drugs manufactured by Janssen Pharmaceuticals, Inc.

49. Janssen manufacturers, promotes, sells, markets, and / or distributes opioids such as Duragesic, Nucynta, and Nucynta ER in the United States, including in Florida. Janssen stopped manufacturing Nucynta and Nucynta ER in 2015.

50. Duragesic and Nucynta ER are Schedule II opioids first approved in 1990 and 2011 respectively.

51. Janssen generates substantial sales revenue from its opioids. For example, Duragesic accounted for more than $1 billion in sales in 2009, and Nucynta and Nucynta ER accounted for $172 million in sales in 2014.

52. Defendant Cephalon, Inc. ("Cephalon") is a Delaware corporation with its principal place of business in Frazer, Pennsylvania.

53. Cephalon manufactures, promotes, sells, and distributes opioids such as Actiq and Fentora in the United States. Actiq has been approved by the FDA only for the "management of breakthrough cancer pain in patients 16 years and older with malignancies who are already receiving and who are tolerant to around-the-clock opioid therapy for the underlying persistent cancer pain."[5] Fentora has been approved by the FDA only for the "management of breakthrough pain in cancer patients 18 years of age and older who are already receiving and who are tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain."[6]

54. In 2008, Cephalon pled guilty to a criminal violation of the Federal Food, Drug and Cosmetic Act for its misleading promotion of Actiq and two other drugs, and agreed to pay a fine in the amount of $425 million.[7]

55. Teva Pharmaceutical Industries, Ltd. ("Teva Ltd.") is an Israeli corporation with its principal place of business in Petah Tikva, Israel. In 2011, Teva Ltd. acquired Cephalon, Inc. Teva Pharmaceutical USA, INC. ("Teva USA") is a Delaware corporation which is registered to

do business in Ohio and is a wholly owned subsidiary of Teva Ltd. in Pennsylvania. Teva USA acquired Cephalon in October 2011.

56. Teva Ltd., Teva USA, and Cephalon, Inc. work together closely to market and sell Cephalon products in the United States. Teva Ltd. conducts all sales and marketing activities for Cephalon in the United States through Teva USA and has done so since its October 2011 acquisition of Cephalon. Teva Ltd. and Teva USA hold out Actiq and Fentora as Teva products to the public. Teva USA sells all former Cephalon branded products through its "specialty medicines" division. The FDA-approved prescribing information and medication guide, which is distributed with Cephalon opioids, discloses that the guide was submitted by Teva USA, and directs physicians to contact Teva USA to report adverse events.

57. Cephalon's promotional websites, including those for Actiq and Fentora, display Teva Ltd.'s logo. Teva Ltd.'s financial reports list Cephalon's and Teva USA's sales as its own, and its year-end report for 2012 – the year immediately following the Cephalon acquisition - attributed a 22% increase in its specialty medicine sales to "the inclusion of a full year of Cephalon's specialty sales," including *inter alia* sales of Fentora®. Through interrelated operations like these, Teva Ltd. operates in the United States through its subsidiaries Cephalon and Teva USA. The United States is the largest of Teva Ltd.'s global markets, representing 53% of its global revenue in 2015, and, were it not for the existence of Teva USA and Cephalon, Inc., Teva Ltd. would conduct those companies' business in the United States itself. Upon information and belief, Teva Ltd. directs the business practices of Cephalon and Teva USA, and their profits inure to the benefit of Teva Ltd. as controlling shareholder. Teva Pharmaceutical Industries, Ltd., Teva Pharmaceuticals USA, Inc., and Cephalon, Inc. are referred to as "Cephalon."

58. Defendant Allergan PLC a public limited company incorporated in Ireland with its principal place of business in Dublin, Ireland. Actavis acquired Allergan PLC, and the combined company changed its name to Allergan PLC. Before that, Watson Pharmaceuticals, Inc. acquired Actavis, Inc. and the combined company changed its name to Actavis, Inc. and then Actavis PLC.

59. Watson Laboratories, Inc. is a Nevada corporation with its principal place of business in Corona, California, and is a wholly-owned subsidiary of Allergan PLC (f/k/a Actavis, Inc., f/k/a Watson Pharmaceuticals, Inc.). Actavis Pharma, Inc. (f/k/a Actavis, Inc.) is registered to do business with the Ohio Secretary of State as a Delaware corporation with its principal place of business in New Jersey and was formerly known as Watson Pharma, Inc.

60. Actavis LLC is a Delaware limited liability company with its principal place of business in Parsippany, New Jersey. Each of these defendants is owned by Allergan PLC, which uses them to market and sell its drugs in the United States. Upon information and belief, Allergan PLC exercises control over these marketing and sales efforts and profits from the sale of Allergan/Actavis products ultimately inure to its benefit. Allergan PLC, Actavis PLC, Actavis, Inc., Actavis LLC, Actavis Pharma, Inc., Watson Pharmaceuticals, Inc., Watson Pharma, Inc., and Watson Laboratories, Inc. are referred to as "Actavis."

61. Actavis manufactures, promotes, sells, and / or distributes opioids, including the branded drugs Kadian and Norco, a generic version of Kadian, and generic versions of Duragesic and Opana, in the United States, including in Florida. Actavis acquired the rights to Kadian from King Pharmaceuticals, Inc. on December 30, 2008, and began marketing Kadian in 2009.

62. Mallinckrodt, PLC is an Irish public limited company headquartered in Stainesupon-Thames, United Kingdom, with its U.S. headquarters in St. Louis, Missouri. Mallinckrodt, LLC is a limited liability company organized and existing under the laws of the State

of Delaware and licensed to do business in Ohio. Mallinckrodt, LLC is a wholly owned subsidiary of Mallinckrodt, PLC. Mallinckrodt, PLC and Mallinckrodt, LLC are referred to as "Mallinckrodt."

63. Mallinckrodt manufactures, markets, and/or sells drugs in the United States including generic oxycodone, of which it is one of the largest manufacturers. In July 2017 Mallinckrodt agreed to pay $35 million to settle allegations brought by the Department of Justice that it failed to detect and notify the DEA of suspicious orders of controlled substances.

64. Defendant Insys Therapuetics, Inc. ("Insys") is a publicly-traded company incorporated in the State of Delaware with it principal place of business at 1333 South Spectrum Bld., Chandler, Arizona.

65. Insys manufactures, markets, and / or sells drugs in the United States including Subsys which is an opioid-fetanyl drug that is approximately fifty times stronger than heroin and one hundred times more potent than morphine.

b. Distributor Defendants

66. At all relevant times, the Distributor Defendants (defined below) have distributed, supplied, sold, and placed into the stream of commerce the prescription opioids, without fulfilling the fundamental duty of wholesale drug distributors to detect and warn of diversion of dangerous drugs for non-medical purposes. The Distributor Distributors universally failed to comply with federal and/or state law. Plaintiff alleges the unlawful conduct by the Distributors is responsible for the volume of prescription opioids plaguing Plaintiff's Community.

67. Defendant McKesson Corporation ("McKesson") is a publicly-traded company incorporated in the State of Delaware with it principal place of business in San Francisco, CA. At

all relevant times, McKesson operated as a licensed pharmacy wholesaler in Florida. McKesson operates distribution centers in Florida.

68. Defendant Cardinal Health, Inc. ("Cardinal") is a publicly-traded company incorporated in the State of Ohio with it principal place of business in Dublin, OH. At all relevant times, Cardinal operated as a licensed pharmacy wholesaler in Florida. Cardinal operates distribution centers in Florida.

c. John and Jane Does 1-100, inclusive

58. The true names, roles, and/or capacities in the wrongdoing alleged herein of Defendants named John and Jane Does 1 through 100, inclusive, are currently unknown to Plaintiff, and thus, are named as Defendants under fictitious names as permitted by the rules of this Court. Plaintiffs will amend this complaint and identify their true identities and their involvement in the wrongdoing at issue, as well as the specific causes of action asserted against them, if and when they become known.

III. JURISDICTION AND VENUE

59. This Court has jurisdiction pursuant to 28 U.S.C. § 1331 and 18 U.S.C. § 1961, *et seq*. as well as 28 U.S.C. § 1332.

60. Venue in this Court is proper under 28 U.S.C. § 1391(b).

IV. FACTUAL ALLEGATIONS

A. Opioids are causing unprecedented harm.

61. Between 1991 and 2011, prescriptions of opioids in the U.S. tripled from 76 million to 219 million per year.[19] Along with that increase in volume, the potency of prescription opioids

[19] Nora D. Volkow, MD, America's Addiction to Opioids. Heroin and Prescription Drug Abuse, Appearing before the Senate Caucus on International Narcotics Control, NIH National Institute on Drug Abuse (May 14, 2014), https/www.drugabuse.gov/about-nida-legislative-activities-testimony-to-congress/2016/americas-addiction-to-opioids-heroin-prescription-drug-abuse.

also increased. By 2002, one in six opioid users were being prescribed drugs more powerful than morphine; by 2012 the ratio had doubled to one in three.[20] And, most troubling, the rise in opioid related overdose deaths has paralleled the increase in prescriptions. On November 1, 2011, the Centers for Disease Control and Prevention ("CDC") declared a "prescription drug epidemic." The CDC was unequivocal about what had caused this epidemic: "prescription opioid painkillers and psychotherapeutic drugs being prescribed more widely by physicians. In the United States, approximately 4,000 deaths involving opioid painkillers were documented in 1999, increasing to 16,234 in 2013, quadrupling in little more than a decade. By 2010, for the first time in history, unintentional drug poisonings represented the leading cause of injury death in the United States, exceeding deaths due to automobile accidents. This scourge has now claimed nearly 200,000 lives, crossing every geographic, economic, and racial boundary.

61. Unsurprisingly, pharmacy retail sales of opioid painkillers, obtained through doctors' prescriptions, quadrupled between 1999 and 2010, coinciding with a quadrupling in prescription-opioid-related deaths. By 2012, prescribers wrote enough opioid painkiller prescriptions to medicate every American adult around the clock for a month. The increase in prescriptions coincided with a well-developed, deceptive, and misleading marketing and advertising campaign by Defendants which significantly downplayed the risks and grossly exaggerated the benefits of the drugs.

62. For millennia, we have understood pain in our lives to serve at least two useful functions. First, pain as a warning system. Second, pain as an opportunity for growth. Today, pain is little valued for these reasons. Instead, pain is regarded as anathema, to be avoided at all

[20] America's opioid epidemic is worsening, the Economist (Mar. 6, 2017), https:www.economist.com/blogs/graphic detail/2017/03/daily-chart-3.

costs. The role of physical pain has likewise undergone a transformation. Today, pain is viewed as an almost intolerable sensation for patients to endure. Doctors no longer aim to lessen pain, but to eliminate it. This new conception of pain has been a major contributor to the prescription drug epidemic. Indeed, prior to 1980, doctors used opioid pain relievers sparingly, and only for the short term in cases of severe injury or illness, or during surgery.[21] Their reluctance to use opioids for an extended length of time, despite their short-term effectiveness for pain, sprang from fear of causing addiction.

63. While prescribing habits have changed, the science has not. Studies have shown that prescription opioids are still simply ineffective tools in managing anything but end-of-life pain or acute pain over very short periods. While there are limited situations where opioid use might be proper, the drugs have potential to cause incredible harm. Despite Defendants' misleading statements that addiction would not or could not happen, patients can become, and often are, quickly addicted to opioids. Sadly, because of Defendants' misleading statements and marketing, millions of Americans have suffered from dependence on, and addiction to deadly opioids.

64. Defendants aggressively and relentlessly pressed to grow the use of their drugs, despite the fact that there has been little or no change in the amount of pain reported in the U.S. over the last twenty years. In fact, the majority of doctors and dentists who prescribe opioids are not pain specialists. For example, a 2014 study conducted by pharmacy benefit manager Express Scripts reviewing narcotic prescription data from 2011-2012 concluded that only 385 of the more than 500,000,000 prescribers of opioids were identified as pain specialists.[22]

[21] Zimmermann M. *History of pain treatment from 1500 to 1900*. Schmerz . 2007;21(4):297–306; Meldrum ML. *Progress in Pain Research and Management* , V. 25. Seattle, WA: IASP Press; 2003.
[22] *A Nation in Pain*, Express Scripts (Dec. 9, 2014), http://lab.expressscripts.com/lab/publications/a-nation-in-pain.

65. The increase in prescriptions of opioids is causing a crisis in this country. For instance, from 1999 to 2015, the rate of opioid-related overdose deaths increased every year. In 1999, opioid overdose deaths totaled approximately 4,030. In 2009, this number rose to 15,597. By 2015, that number rose to more than 33,000, nearly equal to the number of deaths from car crashes. The 33,000 opioid-related deaths in 2015 represented approximately 63% of the more than 52,000 deaths caused by all drug overdoses.[23]

66. In total, more than 183,000 deaths from prescription opioids have been reported in the United States since 1999, and more than half of all opioid overdose deaths involve a prescription opioid, like those manufactured by Defendants.[24] In fact, according to the CDC, someone in the U.S. dies from an overdose of a prescription opioid every sixteen minutes.

67. Further, in 2014 there were 1.27 million emergency room visits or inpatient stays for opioid-related conditions.[25] This is a dramatic increase over the approximately 366,000 emergency department visits related to the misuse or abuse of narcotic pain relievers in 2011.[26] By comparison, in 2011 these visits averaged 1,150 per day. In 2014, the average had climbed to nearly 3,500 visits per day.

[23] *Overdose Death Rates*, NIH National Institute on Drug Abuse, https://www.drugabuse.gov/related-topics/trends-statistics/overdose-death-rates (revised Jan. 2017).
[24] *Understanding the Epidemic*, Centers for Disease Control and Prevention, https://www.cdc.gov/drugoverdose/epidemic/index.html (last updated Aug. 30, 2017).
[25] Audrey J. Weiss, Ph.D., et al., *Patient Characteristics of Opioid-Related Inpatient Stays and Emergency Department Visits Nationally and by State, 2014*, HCUP Statistical Brief #224 (June 2017),https://www.hcup-us.ahrq.gov/reports/statbriefs/sb224-Patient-Characteristics-OpioidHospital-Stays-ED-Visits-by-State.pdf.
[26] Elizabeth H. Crane, Ph.D., *Emergency Department Visits Involving Narcotic Pain Relievers*, Substance Abuse and Mental Health Services Administration (Nov. 5, 2017), https://www.samhsa.gov/data/sites/default/files/report_2083/ShortReport-2083.html.

68. The direct harm caused by Defendants blanketing the country with opioids is staggering—indeed, it has been referred to as "the worst man-made epidemic in modern medical history."[27]

69. The impact does not stop with prescription opioids. As a direct result of opioid abuse, individuals who have become addicted to painkillers—but cannot afford their increased costs or are unable to secure a prescription—have turned to cheaper, more potent, and dangerous alternatives, primarily heroin, fueling another crisis in this country directly attributable to opioid abuse.

70. In 2016, the NEJM published an article examining the relationship between opioids and heroin use. The article concluded that "75% of [heroin] users initiated opioid use with prescription opioids."[28] This study directly links Defendants' deceptive marketing of opioids and the subsequent heroin epidemic in the United States, including in the geographic area where, as well as the individuals to whom, The BHME's provided services.

71. The economic impact of the opioid crisis is devastating. The CDC estimates that the total economic burden of prescription opioid abuse costs the United States $78.5 billion per year, which includes costs of health care, lost productivity, addiction treatment, and criminal justice involvement.[29] One quarter of these costs are borne by the public sector, including by entities like the BHME's.[30]

[27] Gary Franklin, M.D., *Warning: This Drug May Kill You*, HBO, http://www.hbo.com/documentaries/warning-this-drug-may-kill-you/video/how-did-we-gethere.html (last visited Sept. 7, 2017).
[28] Wilson M. Compton, M.D., M.P.E., Christopher M. Jones, Pharm.D., M.P.H., and Grant T. Baldwin, Ph.D., M.P.H., 374 N. Engl. J .Med 154-63 (Jan. 14, 2106), http://www.nejm.org/doi/full/10.1056/NEJMra1508490#ref41.
[29] Wolters Kluwer Health: Lippincott Williams and Wilkins, *Costs of IS prescription opioid epidemic estimated at $78.5 billion*, Science Daily (Sept. 14, 2016), https: www.sciencedailv.com/releases/2016/09/160914105756.htm.
[30] *Id.*

B. Defendants made and continue to make false and misleading statements about opioids through various channels.

72. Despite having knowledge of the profound and devastating impact of opioids on the American public, Defendants have made and continue to make misleading statements about the purported benefits, efficacy, and low risks of opioids—statements that Defendants have failed to completely correct.

73. Defendants effectuated their deceptive marketing campaign by convincing doctors, patients, and the public, among others, that the benefits of using opioids to treat chronic pain outweighed any risks or dangers, and that opioids could be safely used by most patients. They did this despite knowing that the evidence suggesting opioids could be effectively used to treat long-term, chronic pain was and continues to be very weak, while the evidence to suggest opioids cause substantial harm was and continues to be very strong.

74. Specifically, Defendants have made and/or continue to make false or misleading claims in six primary areas: (1) the low risk of addiction to opioids, (2) the need to prescribe more opioids to treat pain, (3) risk-mitigation strategies to safely prescribe opioids, including tapering, (4) the lack of risk associated with higher dosages of opioids, (5) the benefits of abuse- deterrent technology to curb abuse, and (6) that long-term opioid use improves patient function and quality of life. These illustrative but non-exhaustive categories of Defendants' misrepresentations about opioids are described in detail below.

1. Defendants falsely claimed that the risk of opioid addiction was low.

75. According to neuroscientists, addiction is a disorder of the brain's reward circuitry.

76. Doctors rely on the *Diagnostic and Statistical Manual of Mental Disorders* to diagnose addiction (*i.e.*, substance use disorders). The criteria for addiction are sometimes referred to as the three "C's": control, compulsion, and consequences. Control refers to out-of control, especially using more of a substance than intended. Compulsion refers to spending ample time, energy and thought obtaining, using, and recovering from the use of substances. Consequences

refers to the social, legal, economic, interpersonal and moral or spiritual repercussions of continuing to use.

77. The majority of prescription drugs are deemed nonaddictive and are regularly prescribed by doctors with limited restrictions. The Food and Drug Administration ("FDA"), working under the Controlled Substance Act, has organized the drugs posing the greatest risk for misuse, overuse, and addiction into categories of "scheduled drugs." The FDA has delineated a grading system from one to five within the scheduled drugs, with schedule I drugs being the most addictive and schedule V drugs the least addictive. All drugs in schedules II through V are thought to have medical benefit in some situations and can be prescribed by a doctor with a special license. Schedule I drugs, according to federal classification, have no medical benefit and cannot be prescribed by a doctor under any circumstances.

78. Schedule I drugs include heroin, lysergic acid diethylamide (LSD), and methlyenedioxymethamphetamine ("Ecstasy"). Schedule II dugs include most of the opioid painkillers. Doctors can typically give no more than a month's worth of schedule II medication at a time, with no refills allowed. Examples include morphine, opium, codein, hydrocodone (i.e., Vicodin), hydromorphone (Dilaudid), methadone (Dolophine), meperidine (Demerol), oxycodone (OxyContin, Percocet), and fentanyl (Sublimaze, Duragesic).

79. To influence doctor-prescribing, Defendants enlisted the help of paid "thought leaders," paying for these high-priced speakers to travel across the country presenting at seminars and encouraging the doctors attending academic or professional conferences to more liberally prescribe opioids for many types of pain. For example, *New York Times* journalist Barry Meier described how Dr. Russell Portenoy delivered talks across the country that were sponsored by drug

companies or by the Dannemiller Foundation, an organization paid by drug companies to put on continuing medical education programs for doctors.[31]

80. Defendants, directly and indirectly, have made a series of false and misleading statements the effectiveness of opioid therapy and about the low risk of addiction to opioids over the past twenty years, and have failed to take sufficient remedial measures to correct its false and misleading statements. These false and misleading statements have enabled these drugs to remain in schedule II and encouraged their prescription by treating doctors.

81. By way of example, one of the primary and specific claims made by Defendants was that addiction was actually rare in patients treated with opioids. In support of this statement, Defendants cited the 1980 NEJM letter which stated that the "development of addiction is rare in medical patients with no history of addiction."[32] Though the letter's authors stated that they examined the files of 11,882 patients, no analysis was included in the letter. The letter reported that among hospitalized patients taking opioids for pain, clinical researchers had found "only four cases of addiction among 11,882 patients treated with opioids." This misconception – that as long as doctors were prescribing opioids for the treatment of pain, there was less than a 1% chance of their patients becoming addicted – implied, wrongly, that the well-known inherent addictive potential of opioids was eliminated by the halo of a doctor's prescription. We know now that opioid painkillers prescribed by a doctor are as addictive as heroin purchased on a street corner.

82. In addition, the study referenced in the letter analyzed a database of hospitalized patients who were given doses of opioids in a controlled setting to ease suffering from acute pain. These patients were not given long-term opioid prescriptions, nor were they given opioids to

[31] Meier B. *Pain Killer: A Wonder Drug's Trail of Addiction and Death* . New York, NY: St. Martin's Press; 2003.
[32] Jane Porter and Herschel Jick, MD, *Addiction Rare in Patients Treated with Narcotics*, 302(2) N. Engl. J. Med. 123 (Jan. 10, 1980), http://www.nejm.org/doi/pdf/10.1056/NEJM198001103020221.

administer to themselves at home; rather they were treated with opioids under in-hospital doctor supervision.

83. Defendants nevertheless used the letter to tout the purportedly low risk of addiction to the drugs, generally. For example, in its 1996 press release announcing the release of OxyContin, Purdue advertised that the "fear of addiction is exaggerated" and quoted the chairman of the American Pain Society[33] Quality of Care Committee, who claimed that "there is very little risk of addiction from the proper uses of these [opioid] drugs for pain relief."[34]

PR News wire
May 31, 1996. Friday – 15:47 Eastern Time

NEW HOPE FOR MILLIONS OF AMERICANS SUFFERING FROM PERSISTENT

> The fear of addiction is exaggerated. One cause of patient resistance to appropriate pain treatment - the fear of addiction - is largely unfounded. According to Dr. Max, "Experts agree that most pain caused by surgery or cancer can be relieved, primarily by carefully adjusting the dose of opioid (narcotic) pain reliever to each patient's need, and that there is very little risk of addiction from the proper uses of these drugs for pain relief." Paul D. Goldenheim. M.D. Vice President of Purdue Pharma LP. in Norwalk, Connecticut, agrees with this assessment. "Proper use of medication is an essential weapon in the battle against persistent pain. But too often fear, misinformation and poor communication stand in the way of their legitimate use."

84. Dr. Portenoy, a paid Purdue spokesman, also stated in a promotional video from the 1990s that "the likelihood that the treatment of pain using an opioid drug which is prescribed by a doctor will lead to addiction is extremely low."[35]

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[33] The American Pain Society, founded in 1995 with Dr. Portenoy as its first president, issued treatment guidelines urging doctors to prescribe more opioids for the treatment of pain. Their self-proclaimed goal was to cure the medical community of its "opioiphobia" (fear of prescribing opioids).

[34] Press Release, OxyContin, *New Hope for Millions of Americans Suffering from Persistent Pain: Long-Acting OxyContin Tablets Now Available to Relieve Pain* (May 31, 1996), http://documents.latimes.com/oxycontin-press-release-1996/.

[35] Thomas Catan and Evan Perez, *A Pain-Drug Champion Has Second Thoughts*, The Wall Street Journal (Dec. 17, 2012), https://www.wsj.com/articles/SB10001424127887324478304578173342657044604.

85. Purdue also specifically used the 1980 NEJM letter in its 1998 promotional video "I got my life back," in which Dr. Alan Spanos says "In fact, the rate of addiction amongst pain patients who are treated by doctors is much less than 1 %."[36]

86. The 1980 NEJM letter was also used on Purdue's "Partners Against Pain" website, which was available in the early 2000s, where Purdue claimed that the addiction risk with OxyContin was very low.[37]

87. The 1980 NEJM letter was used frequently in literature given to physicians, and in literature given to patients who were prescribed OxyContin.[38]

88. Additionally, Dr. Portenoy used the 1980 NEJM letter as a source in his landmark 1986 paper on the chronic use of opioids, which was based on just 38 patients, all of whom were cancer patients.[39] Because only two of the 38 patients examined became addicted, Portenoy concluded that "opioid maintenance therapy can be a safe, salutary and more humane alternative to the options of surgery or no treatment in those patients with intractable non-malignant pain and no history of drug abuse . . ."[40]

89. Purdue also consistently tried to steer any concern away from addiction, and focus on its false claims that opioids were effective and safe for dealing with chronic pain. At a hearing before the House of Representatives' Subcommittee on Oversight and Investigations of the Committee on Energy and Commerce in August 2001, Michael Friedman, Executive Vice

[36] Our Amazing World, *Purdue Pharma OxyContin Commercial*, https://www.youtube.com/watch?v=Er78Dj5hyeI (last visited Sept. 7, 2017) (emphasis added).
[37] Art Van Zee, M.D., *The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy*, 99(2) Am J Public Health 221-27 (Feb. 2009), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2622774/.
[38] AArt Van Zee, M.D., *The OxyContin Abuse Problem: Spotlight on Purdue Pharma's Marketing* (Aug. 22, 2001), https://www.fda.gov/ohrms/dockets/dockets/01n0256/c000297A.pdf.
[39] Russel K. Portenoy and Kathleen M. Foley, *Chronic Use of Opioid Analgesics in NonMalignant Pain: Report of 38 Cases*, 25 Pain 171-86 (1986), https://fellowiki.wikispaces.com/file/view/PAIN+CHRONIC+USE+OF+OPIOIDS.pdf.
[40] *Id.*

President and Chief Operating Officer of Purdue, testified that "even the most vocal critics of opioid therapy concede the value of OxyContin in the legitimate treatment of pain," and that "OxyContin has proven itself an effective weapon in the fight against pain, returning many patients to their families, to their work, and to their ability to enjoy life."[41]

90. At this same hearing, Purdue continued to emphasize "legitimate" treatment, dismissing cases of overdose and death as something that would not befall "legitimate" patients: "Virtually all of these reports involve people who are abusing the medication, not patients with legitimate medical needs under the treatment of a healthcare professional."[42]

91. Purdue spun this baseless "legitimate use" distinction out even further in a patient brochure about OxyContin, called "A Guide to Your New Pain Medicine and How to Become a Partner Against Pain." In response to the question, "Aren't opioid pain medications like OxyContin Tablets 'addicting'? Even my family is concerned about this," Purdue claimed that there was no need to worry about addiction if taking opioids for legitimate, "medical" purposes:

> Drug addiction means using a drug to get "high" rather than to relieve pain. You are taking opioid pain medication for medical purposes. The medical purposes are clear and the effects are beneficial, not harmful.

92. Similarly, a Senior Medical Director for Purdue, Dr. David Haddox, cavalierly stated, "[w]hen this medicine is used appropriately to treat pain under a doctor's care, it is not only effective, it is safe."[43] He went so far as to compare OxyContin to celery, because even celery

[41] *Oxycontin: Its Use and Abuse: Hearing Before the H. Subcomm. on Oversight and Investigations of the Comm. on Energy and Commerce*, 107th Cong. 1 (Aug. 28, 2001) (statement of Michael Friedman, Executive Vice President, Chief Operating Officer, Purdue Pharma, L.P.), https://www.gpo.gov/fdsys/pkg/CHRG107hhrg75754/html/CHRG107hhrg75754.htm.
[42] *Id.*
[43] Roger Alford, *Deadly OxyContin abuse expected to spread in the U.S.*, Charleston Gazette, Feb. 9, 2001.

would be harmful if injected: "If I gave you a stalk of celery and you ate that, it would be healthy for you. But if you put it in a blender and tried to shoot it into your veins, it would not be good."[44]

93. Purdue sales representatives also repeated these misstatements regarding the low risk for addiction to doctors across the country.[45] Its sales representatives targeted primary care physicians in particular, downplaying the risk of addiction and, as one doctor observed, "promot[ing] among primary care physicians a more liberal use of opioids."[46] Purdue also marketed OxyContin for a wide variety of conditions and to doctors who were not adequately trained in pain management.[47]

94. As of 2003, Purdue's Patient Information guide for OxyContin contained the following language regarding addiction:

> Concerns about abuse, addiction, and diversion should not prevent the proper management of pain. The development of ***addiction to opioid*** analgesics in properly managed patients with pain ***has been reported to be rare***. However, data are not available to establish the true incidence of addiction in chronic pain patients.
>
> *Emphasis added.*

95. Although Purdue has acknowledged it has made some misrepresentations about the safety of its opioids,[48] it has done nothing to address the ongoing harms of their misrepresentations; in fact, it continues to make those misrepresentations today.

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[44] *Id.*
[45] Barry Meier, *In Guilty Plea, OxyContin Maker to Pay $600 Million*, The New York Times (May 10, 2007), http://www.nytimes.com/2007/05/10/business/11drug-web.html.
[46] Art Van Zee, M.D., *The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy*, 99(2) Am J Public Health 221-27 (Feb. 2009), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2622774/.
[47] *OxyContin Abuse and Diversion and Efforts to Address the Problem*, U.S. General Accounting Office Report to Congressional Requesters (Dec. 2003), http://www.gao.gov/new.items/d04110.pdf.
[48] Following the conviction in 2007 of three of its executives for misbranding OxyContin, Purdue released a statement in which they acknowledged their false statements. "Nearly six years and longer ago, some employees made, or told other employees to make, certain statements about OxyContin to some health care professionals that were inconsistent with the F.D.A. approved prescribing information for OxyContin and the express warnings it contained about risks associated with the medicine. The statements also violated written company policies requiring adherence to the prescribing information."

96. By way of further example, Defendant Endo also made dubious claims about the low risk of addiction. For instance, it sponsored a website, PainKnowledge.com, on which in 2009 it claimed that "[p]eople who take opioids as prescribed usually do not become addicted."[49] The website has since been taken down.

97. In another website, PainAction.com—which is still currently available today—Endo also claimed that "most chronic pain patients do not become addicted to the opioid medications that are prescribed for them."[50]

98. In addition, Endo made statements in pamphlets and publications that most health care providers who treat people with pain agree that most people do not develop an addiction problem, and that taking opioids for pain relief is not an addiction. These statements also appeared on websites sponsored by Endo, such as Opana.com.

99. In its currently active website, PrescribeResponsibly.com, Defendant Janssen states that concerns about opioid addiction are "overestimated" and that "true addiction occurs only in a small percentage of patients."[51]

100. Similarly, in a 2009 patient education video titled "Finding Relief: Pain Management for Older Adults," Janssen sponsored a video by the American Academy of Pain Medicine that indicated that opioids are rarely addictive. The video has since been taken down.[52]

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[49] German Lopez, *US officials are starting to treat opioid companies like Big Tobacco—and suing them*, Vox (Aug.9, 2017), https://www.vox.com/policy-andpolitics/2017/6/7/15724054/opioid-companies-epidemic-lawsuits.

[50] *Opioid medication and addiction*, Pain Action (Aug. 17, 2017), https://www.painaction.com/opioid-medication-addiction.

[51] Keith Candiotti, M.D., *Use of Opioid Analgesics in Pain Management*, Prescribe Responsibly, http://www.prescriberesponsibly.com/articles/opioid-pain-management (last modified Jul. 2, 2015).

[52] Molly Huff, *Finding Relief: Pain Management for Older Adults*, Centers for Pain Management (Mar. 9, 2011), http://www.managepaintoday.com/news/-Finding-Relief-Pain-Management-forOlder-Adults.

101. Janssen also approved and distributed a patient education guide in 2009 that attempted to counter the "myth" that opioids are addictive, claiming that "[m]any studies show that opioids are rarely addictive when used properly for the management of chronic pain."[53]

102. In addition, Defendants used third parties and Front Groups to further their false and misleading statements about the safety of opioids.

103. For example, in testimony for the Hearing to Examine the Effects of the Painkiller OxyContin, Focusing on Risks and Benefits, in front of the Senate Health, Education, Labor and Pensions Committee in February 2002, Dr. John D. Giglio, Executive Director of the APF, the organization which, as described above, received the majority of its funding from opioid manufacturers, including Purdue, stated that "opioids are safe and effective, and only in rare cases lead to addiction."[54]

104. The APF further backed up Purdue in an amicus curiae brief filed in an Ohio appeals court in December 2002, in which it claimed that "medical leaders have come to understand that the small risk of abuse does not justify the withholding of these highly effective analgesics from chronic pain patients."[55]

105. In a 2007 publication titled "Treatment Options: A Guide for People Living with Pain," APF downplayed the risk of addiction and argued that concern about this risk should not prevent people from taking opioids: "Restricting access to the most effective medications for

[53] German Lopez, *US officials are starting to treat opioid companies like Big Tobacco—and suing them*, Vox (Aug. 9, 2017), https://www.vox.com/policy-andpolitics/2017/6/7/15724054/opioid-companies-epidemic-lawsuits.
[54] *Oxycontin: Balancing Risks and Benefits: Hearing of the S. Comm. on Health, Education, Labor and Pensions*, 107th Cong. 2 (Feb. 12, 2002) (testimony of John D. Giglio, M.A., J.D., Executive Director, American Pain Foundation), https://www.help.senate.gov/imo/media/doc/Giglio.pdf.
[55] Brief Amici Curiae of American Pain Foundation, National Foundation for the Treatment of Pain, and The Ohio Pain Initiative, in Support of Defendants/Appellants, *Howland v. Purdue Pharma, L.P., et al*., Appeal No. CA 2002 09 0220 (Butler Co., Ohio 12th Court of Appeals, Dec. 23, 2002), https://ia801005.us.archive.org/23/items/279014-howland-apf-amicus/279014howland-apf-amicus.pdf.

treating pain is not the solution to drug abuse or addiction." APF also tried to normalize the dangers of opioids by listing opioids as one of several "[c]ommon drugs that can cause physical dependence," including steroids, certain heart medications, and caffeine.

106. As set forth in more detail below, these statements were false and misleading as evidenced by, *inter alia*, the findings made by the CDC in 2016.

2. Defendants falsely instructed doctors and patients that more opioids were the solution when patients presented symptoms of addiction.

107. Not only did Defendants hide the serious risks of addiction associated with opioids, they actively worked to prevent doctors from taking steps to prevent or address opioid addiction in their patients.

108. One way that Defendants worked to obstruct appropriate responses to opioid addiction was to push a concept called "pseudoaddiction." Dr. David Haddox—who later became a Senior Medical Director for Purdue—published a study in 1989 coining the term, which he characterized as "the iatrogenic syndrome of abnormal behavior developing as a direct consequence of inadequate pain management."[56] In other words, he claimed that people on prescription opioids who exhibited classic signs of addiction were not, in fact, addicted to opioids, but rather simply suffering from improperly managed pain—specifically, under- treatment. His solution for "pseudoaddiction"? More opioids. Although this concept was formed based on a single case study, it proved to be a favorite trope in Defendants' marketing schemes.

109. For example, using this study, Purdue informed doctors and patients that signs of addiction are actually the signs of under-treated pain which should be treated with even more opioids. Purdue reassured doctors and patients, telling them, without any apparent evidence, that

[56] David E. Weissman and J. David Haddox, *Opioid pseudoaddiction--an iatrogenic syndrome*, 36(3) Pain 363-66 (Mar. 1989), https://www.ncbi.nlm.nih.gov/pubmed/2710565.

"chronic pain has been historically undertreated."[57]

110. Defendants continued to spread the concept of pseudoaddiction through the APF, which even went so far as to compare opioid addicts to coffee drinkers. In a 2002 court filing, APF wrote that "[m]any pain patients (like daily coffee drinkers) claim they are 'addicted' when they experience withdrawal symptoms associated with physical dependence as they decrease their dose. But unlike actual addicts, such individuals, if they resume their opioid use, will only take enough medication to alleviate their pain . . ."[58]

111. In a 2007 publication titled "Treatment Options: A Guide for People Living with Pain," the APF claimed: "Physical dependence is normal, any patient who is taking an opioid on a regular basis for a few days should be assumed to be physically dependent. This does NOT mean you are addicted."[59] In this same publication, when describing behaviors of addiction, the APF again used the idea of pseudoaddiction, claiming that people who are not substance abusers may also engage in behaviors that mirror those of actual addicts.

112. Purdue published a Risk Evaluation and Mitigation Strategy ("REMS") for OxyContin in 2010, and in the associated Healthcare Provider Training Guide stated that "[b]ehaviors that suggest drug abuse exist on a continuum, and pain-relief seeking behavior can be mistaken for drug-seeking behavior."[60]

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[57] *Oxycontin: Its Use and Abuse: Hearing Before the H. Subcomm. on Oversight and Investigations of the Comm. on Energy and Commerce*, 107th Cong. 1 (Aug. 28, 2001) (statement of Michael Friedman, Executive Vice President, Chief Operating Officer, Purdue Pharma, L.P.), https://www.gpo.gov/fdsys/pkg/CHRG107hhrg75754/html/CHRG107hhrg75754.htm.

[58] Brief Amici Curiae of American Pain Foundation, National Foundation for the Treatment of Pain, and The Ohio Pain Initiative, in Support of Defendants/Appellants, *Howland v. Purdue Pharma, L.P., et al*., Appeal No. CA 2002 09 0220 (Butler Co., Ohio 12th Court of Appeals, Dec. 23, 2002), https://ia801005.us.archive.org/23/items/279014-howland-apf-amicus/279014howland-apf-amicus.pdf.

[59] *Treatment Options: A Guide for People Living with Pain*, American Pain Foundation, https://assets.documentcloud.org/documents/277605/apf-treatmentoptions.pdf (last visited Sept. 7, 2017).

[60] *OxyContin Risk Evaluation and Mitigation Strategy*, Purdue Pharma L.P., https://www.fda.gov/downloads/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/UCM220990.pdf (last modified Nov. 2010).

113. Purdue worked, and continues to work, to create confusion about what addiction is. For example, Purdue continues to emphasize that abuse and addiction are separate and distinct from physical dependence. Regardless of whether these statements may be technically correct, they continue to add ambiguity over the risks and benefits of opioids.

114. Endo sponsored a National Initiative on Pain Control (NIPC) CME program in 2009 which promoted the concept of pseudoaddiction by teaching that a patient's aberrant behavior was the result of untreated pain. Endo substantially controlled NIPC by funding its projects, developing content, and reviewing NIPC materials.

115. A 2001 study which was authored by a doctor affiliated with Janssen stated that "[m]any patients presenting to a doctor's office asking for pain medications are accused of drug seeking. In reality, most of these patients may be undertreated for their pain syndrome."[61]

116. In 2009, on a website it sponsored, Janssen stated that pseudoaddiction is different from true addiction "because such behaviors can be resolved with effective pain management."[62]

117. Indeed, on its currently active website PrescribeResponsibly.com, Janssen defines pseudoaddiction as "a syndrome that causes patients to seek additional medications due to inadequate pharmacotherapy being prescribed. Typically, when the pain is treated appropriately, the inappropriate behavior ceases."[63]

118. As set forth in more detail below, these statements were false and misleading as evidenced by, inter alia, the findings made by the CDC in 2016.

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[61] Howard A. Heit, MD, FACP, FASAM, *The truth about pain management: the difference between a pain patient and an addicted patient*, 5 European Journal of Pain 27-29 (2001), http://www.med.uottawa.ca/courses/totalpain/pdf/doc-34.pdf.

[62] Chris Morran, *Ohio: Makers Of OxyContin, Percocet & Other Opioids Helped Fuel Drug Epidemic By Misleading Doctors, Patients*, Consumerist (May 31, 2017), https://consumerist.com/2017/05/31/ohio-makers-of oxycontin-percocet-other-opioids-helped- fuel drug-epidemic-by-misleading-doctors-patients/.

[63] Howard A. Heit, MD, FACP, FASAM and Douglas L. Gourlay, MD, MSc, FRCPC, FASAM, *What a Prescriber Should Know Before Writing the First Prescription, Prescribe Responsibly*, http://www.prescriberesponsibly.com/articles/before-prescribing-opioids#pseudoaddiction (last modified July 2, 2015).

3. Defendants falsely claimed that risk-mitigation strategies, including tapering, could safely address any concerns about addiction.

119. Even when Defendants acknowledge there are addiction risks in the use of opioids, they dismiss these concerns by claiming that addiction can be easily avoided and addressed through simple steps. That is false. No one knows for sure what causes addiction, but decades of accumulated evidence point to certain risk factors, which can be broadly divided into three categories: nature, nurture, and neighborhood. As the neuroscientist Roy Wise, who studies addiction in animals, says the only way an addicted animal will stop using drugs is if the drug is no longer available, the animal is too physically exhausted to administer the drug, or the animal dies.[64] While humans are different, recovery from addiction is a life-long struggle, requiring life-long treatment or monitoring. In other words, Defendants falsely communicated to doctors and patients that certain screening tools would allow them to reliably identify risks and safely prescribe opioids to patients, and that tapering the dose would be sufficient to manage cessation of opioid treatment. Both assertions are false.

120. By way of example, as noted above, Purdue published a REMS for OxyContin in 2010, in which it described certain steps that needed to be followed for safe opioid use. Purdue stressed that all patients should be screened for their risk of abuse or addiction, and that such screening could curb the incidence of addiction.[65]

121. The APF also proclaimed in a 2007 booklet, sponsored in part by Purdue, that "[p]eople with the disease of addiction may abuse their medications, engaging in unacceptable behaviors like increasing the dose without permission or obtaining the opioid from multiple

[64] Wise R, Koob GF. The development and maintenance of drug addiction. Neuropsychopharmacology, 2014; 39(2):254–262.

[65] *Oxycontin Risk Evaluation and Mitigation Strategy*, Purdue Pharma L.P., https://www.fda.gov/downloads/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/UCM220990.pdf (last modified Nov. 2010).

sources, among other things. Opioids get into the hands of drug dealers and persons with an addictive disease as a result of pharmacy theft, forged prescriptions, Internet sales, and even from other people with pain. It is a problem in our society that needs to be addressed through many different approaches."[66]

122. On its current website for OxyContin,[67] Purdue acknowledges that certain patients have higher risk of opioid addiction based on history of substance abuse or mental illness—a statement which, even if accurate, obscures the significant risk of addiction for all patients, including those without such a history, and comports with statements it has recently made that it is "bad apple" patients, and not the opioids, that are arguably the source of the opioid crisis:

123. Additionally, on its current website, Purdue refers to publicly available tools that can assist with prescribing compliance, such as patient-prescriber agreements and risk assessments—however, the link to these documents appears to be no longer active.[68]

124. Purdue continues to downplay the severity of addiction and claims that dependence can easily be overcome by strategies such as adhering to a tapering schedule to successfully stop opioid treatment. On the current website for OxyContin, it instructs that "[w]hen discontinuing OxyContin, gradually taper the dosage. Do not abruptly discontinue OxyContin."[69] And on the current OxyContin Medication Guide, Purdue also states that one should "taper the dosage gradually."[70]

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[66] *See supra* note 49.
[67] OxyContin, https://www.oxycontin.com/index.html
[68] *ER/LA Opioid Analgesics REMS*, Purdue, http://www.purduepharma.com/healthcareprofessionals/responsible-use-of-opioids/rems/ (last visited Nov. 22, 2017).
[69] See supra note 51.
[70] *OxyContin Full Prescribing Information*, Purdue Pharma LP, http://app.purduepharma.com /xmlpublishing/pi.aspx?id=o (last visited Nov. 22, 2017).

125. In its "Dear Healthcare Professional" letter in 2010, Purdue instructed doctors to gradually taper someone off of OxyContin to prevent signs and symptoms of withdrawal in patients who were physically dependent.[71] Nowhere does Purdue warn doctors or patients that tapering may be inadequate to safely end opioid treatment and avoid addiction.

126. Endo also suggests that risk-mitigation strategies enable the safe prescription of opioids. In its currently active website, Opana.com, Endo states that assessment tools should be used to assess addiction risk, but that "[t]he potential for these risks should not, however, prevent proper management of pain in any given patient."[72]

127. On the same website, Endo addresses tapering by stating "[w]hen discontinuing OPANA ER, gradually taper the dosage."[73]

128. Janssen states on its currently active website, PrescribeResponsibly.com, that opioid addiction "can usually be managed" and that tools such as Opioid Agreements between patients and doctors can aid with this.

129. Each Defendant's statements about tapering misleadingly implied that gradual tapering would be sufficient to alleviate any risk of withdrawal or addiction while taking opioids.

130. As set forth in more detail below, these statements were false and misleading as evidenced by, inter alia, the findings made by the CDC in 2016.

4. Defendants falsely claimed doctors and patients could increase opioid usage indefinitely without added risk and failed to disclose risks associated with higher dosages.

131. Defendants also made false and misleading statements regarding the volume of opioid use by patients, statements that were especially beneficial for Defendants' profits.

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[71] *See supra* note 49.
[72] Opana ER, http://www.opana.com (last visited Nov. 22, 2017).
[73] *Id.*

132. For example, in 2012, APF claimed on its website that there was no "ceiling dose" for opioids for chronic pain.[74] APF also made this claim in a guide sponsored by Purdue, which is still available online.

133. In a 1996 sales strategy memo from a Purdue regional manager, the manager emphasized that representatives should "convinc[e] the physician that there is no need" for prescribing OxyContin in shorter intervals than the recommended 12-hour interval, and instead the solution is prescribing higher doses. The manager directed representatives to discuss with physicians that there is "no[] upward limit" for dosing and ask "if there are any reservations in using a dose of 240mg-320mg of OxyContin."[75]

134. In fact, the 2003 Conversion Guide for OxyContin contained the following diagram for increasing dosage up to 320 mg:

135. Purdue's 2010 REMS for OxyContin also does not address concerns with increasing dosage, and instead advises prescribers that "dose adjustments may be made every 1-2 days"; "it is most appropriate to increase the ql2h dose"; the "total daily dose can usually be increased by 25% to 50%"; and if "significant adverse reactions occur, treat them aggressively until they are under control, then resume upward titration."[76]

136. In a 2004 response letter to the FDA, Purdue tried to address concerns that patients who took OxyContin more frequently than 12 hours would be at more risk of side effects or adverse reactions. Purdue contended that the peak plasma concentrations of oxycodone would not increase with more frequent dosing, and therefore no adjustments to the package labeling or 12-hour dosing

[74] Noah Nesin, M.D., FAAFP, *Responsible Opioid Prescribing*, PCHC, https://www.mainequalitycounts.org /image_upload/Keynote-%20Managing%20Chronic%20Pain%20and%20Opioids_Nesin.pdf (last visited Sept. 7, 2017).
[75] *Sales manager on 12-hour dosing*, Los Angeles Times (May 5, 2016), http://documents.latimes.com/sales-manager-on12-hour-dosing-1996/.
[76] *See supra* note 49.

regimen were needed.[77] But these claims were false, and Purdue's suggestion that there was no upper limit or risk associated with increased dosage was incredibly misleading.

137. Contrary to these claims of no upward limit of dosing, Purdue discontinued its 160mg tablet in 2007 and stated that this step was taken "to reduce the risk of overdose accompanying the abuse of this dosage strength."[78]

138. Accordingly, Purdue continued to represent both publicly and privately that increased opioid usage was safe and did not present additional risk at higher doses.

139. Endo, on a website it sponsors, PainKnowledge.com, also made the claim in 2009 that opioid dosages could be increased indefinitely.

140. In a publication titled "Understanding Your Pain: Taking Oral Opioid Analgesics," Endo assures opioid users that concern about developing tolerance to the drugs' pain-relieving effect is "not a problem," and that "[t]he dose can be increased" and "[y]ou won't 'run out' of pain relief."[79]

141. Janssen also discussed the disadvantages of dosage limits for other pain medicines in a 2009 patient education guide, but failed to address the risks of dosage increases with opioids.

142. As set forth in more detail below, these statements were false and misleading as evidenced by, inter alia, the findings made by the CDC in 2016.

5. Defendants' deceptive marketing of the purported abuse-deterrent properties of their opioids has created false impressions that reformulated opioids can curb addiction and abuse.

[77] *Purdue Response to FDA, 2004*, Los Angeles Times (May 5, 2016), http://documents.latimes.com/purdue-response-fda-2004/.
[78] *OxyContin Tablets Risk Management Program*, Purdue Pharma L.P., https://www.fda.gov/ohrms/dockets/DOCKETS/07p0232/07p-0232-cp00001-03-Exhibit-02Part-1-vol1.pdf (revised May 18, 2007).
[79] *Understanding Your Pain: Taking Oral Opioid Analgesics*, Endo Pharmaceuticals (2004), http://www.thblack.com/links/RSD/Understand_Pain_Opioid_Analgesics.pdf.

143. Defendants have also made and continue to make false and misleading statements about the purported abuse-deterrent properties of their opioid pills to suggest these reformulated pills are not susceptible to abuse. In so doing, Defendants have increased their profits by selling more pills for substantially higher prices.

144. For instance, since at least 2001, Purdue has contended that "abuse resistant products can reduce the incidence of abuse."[80] Its current website touts abuse-deterrent properties by saying they "can make a difference."[81]

145. On August 17, 2015, Purdue announced the launch of a new website, "Team Against Opioid Abuse," which it said was "designed to help healthcare professionals and laypeople alike learn about different abuse-deterrent technologies and how they can help in the reduction of misuse and abuse of opioids."[82] This website appears to no longer be active.

146. A 2013 study which was authored by at least two doctors who at one time worked for Purdue stated that "[a]buse-deterrent formulations of opioid analgesics can reduce abuse."[83] In another study from 2016 with at least one Purdue doctor as an author, the authors claimed that abuse decreased by as much as 99% in some situations after abuse-deterrent formulations were introduced.[84]

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[80] *Oxycontin: Its Use and Abuse: Hearing Before the H. Subcomm. on Oversight and Investigations of the Comm. on Energy and Commerce*, 107th Cong. 1 (Aug. 28, 2001) (statement of Michael Friedman, Executive Vice President, Chief Operating Officer, Purdue Pharma, L.P.), https://www.gpo.gov/fdsys/pkg/CHRG-107hhrg75754/html/CHRG107hhrg75754.htm.

[81] *Opioids with Abuse-Deterrent Properties*, Purdue, http://www.purduepharma.com/healthcareprofessionals/responsible-use-of-opioids/opioids-with-abuse-deterrent-properties/ (last visited Sept. 7, 2017).

[82] *Purdue Pharma L.P. Launches TeamAgainstOpioidAbuse.com*, Purdue (Aug. 17, 2015), http://www.purduepharma.com/news-media/2015/08/purdue-pharma-l-p-launchesteamagainstopioidabuse-com/.

[83] Paul M. Coplan, Hrishikesh Kale, Lauren Sandstrom, Craig Landau, and Howard D. Chilcoat, *Changes in oxycodone and heroin exposures in the National Poison Data System after introduction of extended-release oxycodone with abuse-deterrent characteristics*, 22 (12) Parmacoepidemiol Drug Saf. 1274-82 (Sept. 30, 2013), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4283730/.

[84] Paul M. Coplan, Howard D. Chilcoat, Stephen Butler, Edward M. Sellers, Aditi Kadakia, Venkatesh Harikrishnan, J. David Haddox, and Richard C. Dart, *The effect of an abuse-deterrent opioid formulation (OxyContin) on opioid abuse-related outcomes in the postmarketing setting*, 100 Clin. Pharmacol. Ther., 275-86 (June 22, 2016), http://onlinelibrary.wiley.com/doi/10.1002/cpt.390/full.

147. Interestingly, one report found that the original safety label for OxyContin, which instructed patients not to crush the tablets because it would have a rapid release effect, may have inadvertently given opioid users ideas for techniques to get high from these drugs.[85]

148. In 2012, Defendant Endo replaced the formula for Opana ER with a new formula with abuse-deterrent properties that it claimed would make Opana ER resistant to manipulation from users to snort or inject it. Despite the FDA determining that the data did not back up claims that the new formula could reduce abuse, Endo advertised its reformulated pills as "crush resistant" and directed its sales representatives to represent the same to doctors. In 2016, Endo reached an agreement with the Attorney General of the State of New York that required Endo to discontinue making such statements.[86]

149. Defendants' assertions that their reformulated pills could curb abuse were false and misleading, as the CDC's 2016 Guidelines, discussed below, confirm.

6. Defendants falsely claimed that long-term opioid use improved patients' function and quality of life.

150. Not only did Defendants falsely claim there were minimal or no harms associated with opioid use, Defendants represented that there was a significant upside to long-term opioid use, including that opioids could restore function.

151. Purdue, for example, sponsored the development and distribution of an APF guide in 2011 which claimed that "multiple clinical studies have shown that opioids are effective in

[85] *OxyContin Abuse and Diversion and Efforts to Address the Problem*, U.S. General Accounting Office Report to Congressional Requesters (Dec. 2003), http://www.gao.gov/new.items/d04110.pdf.
[86] Press Release, Attorney General Eric T. Schneiderman, *A.G. Schneiderman Announces Settlement with Endo Health Solutions Inc. & Endo Pharmaceuticals Inc. Over Marketing of Prescription Opioid Drugs* (Mar. 3, 2016), https://ag.ny.gov/press-release/ag-schneidermanannounces-settlement-endo-health-solutions-inc-endo-pharmaceuticals.

improving daily function, psychological health, and health-related quality of life for chronic pain patients." This guide is still available today.

152. Purdue also ran a series of advertisements of OxyContin in 2012 in medical journals titled "Pain vignettes,"" which were styled as case studies of patients with persistent pain conditions and for whom OxyContin was recommended to improve their function.

153. Purdue and Endo also sponsored and distributed a book in 2007 to promote the claim that pain relief from opioids, by itself, improved patients' function. The book remains for sale online today.

154. Endo's advertisements for Opana ER claimed that use of the drug for chronic pain allowed patients to perform demanding tasks like construction and portrayed Opana ER users as healthy and unimpaired.

155. Endo's N1PC website also claimed in 2009 that with opioids, "your level of function should improve; you may find you are now able to participate in activities of daily living, such as work and hobbies, that you were not able to enjoy when your pain was worse."

156. Endo further sponsored a series of CME programs through N1PC which claimed that chronic opioid therapy has been "shown to reduce pain and depressive symptoms and cognitive functioning."

157. Through PainKnowledge.org, Endo also supported and sponsored guidelines that stated, among other things, that "Opioid Medications are a powerful and often highly effective tool in treating pain," and that "they can help restore comfort, function, and quality of life."[87]

158. In addition, Janssen sponsored and edited patient guides which stated that "opioids may make it easier for people to live normally." The guides listed expected functional

[87] *Informed Consent for Using Opioids to Treat Pain*, Painknowledge.org (2007), https://www.mainequalitycounts.org /image_upload/Opioid%20Informed%20Consent%20Format ted_1_23_2008.pdf

improvements from opioid use, including sleeping through the night, and returning to work, recreation, sex, walking, and climbing stairs.

159. Janssen also sponsored, funded, and edited a website which featured an interview edited by Janssen that described how opioids allowed a patient to "continue to function." This video is still available today.

160. Furthermore, sales representatives for Purdue, Endo, and Janssen communicated and continue to communicate the message that opioids will improve patients' function, without appropriate disclaimers.

161. Defendants' statements regarding opioids' ability to improve function and quality of life are false and misleading. As the CDC's 2016 Guidelines confirm, not a single study supports these claims.

C. The 2016 CDC Guidelines and other recent studies confirm that Defendants' statements about the risks and benefits of opioids are patently false.

162. Contrary to the statements made by Defendants in their well-orchestrated campaign to tout the benefits of opioids and downplay their risks, recent studies confirm Defendants' statements were false and misleading.

163. The CDC issued its Guideline for Prescribing Opioids for Chronic Pain on March 15, 2016 (the "2016 CDC Guideline" or "Guideline").[88] The 2016 CDC Guideline, approved by the FDA, "provides recommendations for primary care clinicians who are prescribing opioids for chronic pain outside of active cancer treatment, palliative care, and end-of-life care." The Guideline also assesses the risks and harms associated with opioid use.

[88] Deborah Dowell, M.D., Tamara M. Haegerich, Ph.D., and Roger Chou, M.D., *CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016*, Centers for Disease Control and Prevention (Mar. 18, 2016), https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm.

164. The 2016 CDC Guideline was issued after the CDC "obtained input from experts, stakeholders, the public, peer reviewers, and a federally chartered advisory committee." The recommendations in the 2016 CDC Guideline were further made "on the basis of a systematic review of the best available evidence.

165. With respect to the expert opinions obtained by the CDC for the Guideline, the

CDC went through an extensive and detailed process to solicit these opinions. For instance, the Guideline indicates as follows:

> CDC sought the input of experts to assist in reviewing the evidence and providing perspective on how CDC used the evidence to develop the draft recommendations. These experts, referred to as the "Core Expert Group" (CEG) included subject matter experts, representatives of primary care professional societies and state agencies, and an expert in guideline development methodology. CDC identified subject matter experts with high scientific standing; appropriate academic and clinical training and relevant clinical experience; and proven scientific excellence in opioid prescribing, substance use disorder treatment, and pain management. CDC identified representatives from leading primary care professional organizations to represent the audience for this guideline. Finally, CDC identified state agency officials and representatives based on their experience with state guidelines for opioid prescribing that were developed with multiple agency stakeholders and informed by scientific literature and existing evidence-based guidelines.

166. The 2016 Guideline was also peer-reviewed pursuant to "the final information quality bulletin for peer review." In particular, the Guideline indicates:

> [P]eer review requirements applied to this guideline because it provides influential scientific information that could have a clear and substantial impact on public- and private-sector decisions. Three experts independently reviewed the guideline to determine the reasonableness and strength of recommendations; the clarity with which scientific uncertainties were clearly identified; and the rationale, importance, clarity, and ease of implementation of the recommendations. CDC selected peer reviewers based on expertise, diversity of scientific viewpoints, and independence from the guideline development process. CDC assessed and managed potential conflicts of interest using a process similar to the one as described for solicitation of expert opinion. No financial interests were identified in the disclosure and review process, and nonfinancial activities were determined to be of minimal risk; thus, no significant conflict of interest concerns were identified.

167. Accordingly, there is no doubt that the 2016 CDC Guideline is the result of a thorough and extensive process by the CDC.

168. The findings in the 2016 CDC Guideline both confirmed the existing body of scientific evidence regarding the questionable efficacy of opioid use and contradicted Defendants' statements about opioids.

169. For instance, the Guideline states "[e]xtensive evidence shows the possible harms of opioids (including opioid use disorder, overdose, and motor vehicle injury)" and that "[o]pioid pain medication use presents serious risks, including overdose and opioid use disorder." The Guideline further confirms there are significant symptoms related to opioid withdrawal, including drug cravings, anxiety, insomnia, abdominal pain, vomiting, diarrhea, sweating, tremor, tachycardia (rapid heartbeat), spontaneous abortion and premature labor in pregnant women, and the unmasking of anxiety, depression, and addiction. These findings contradict statements made by Defendants regarding the minimal risks associated with opioid use, including that the risk of addiction from opioid use is low.

170. The Guideline also alarmingly states that there is "[n]o evidence" to show "a long-term benefit of opioids in pain and function versus no opioids for chronic pain . . ." Furthermore, the Guideline indicates that "continuing opioid therapy for 3 months substantially increases the risk of opioid use disorder." Indeed, the Guideline also indicates that "[p]atients who do not experience clinically meaningful pain relief early in treatment ... are unlikely to experience pain relief with longer-term use," and that physicians should 'reassess[] pain and function within 1 month" in order to decide whether to "minimize risks of long-term opioid use by discontinuing opioids" because the patient is "not receiving a clear benefit." These findings flatly contradict

claims made by Defendants that there are minimal or no adverse impacts of long-term opioid use, or that long-term opioid use could actually improve or restore a patient's function.

171. In support of these statements about the lack of long-term benefits of opioid use, the CDC concluded that "[a]lthough opioids can reduce pain during short-term use, the clinical evidence review found insufficient evidence to determine whether pain relief is sustained and whether function or quality of life improves with long-term opioid therapy." The CDC further found that "evidence is limited or insufficient for improved pain or function with long-term use of opioids for several chronic pain conditions for which opioids are commonly prescribed, such as low back pain, headache, and fibromyalgia."

172. With respect to opioid dosing, the Guideline reports that "benefits of high-dose opioids for chronic pain are not established" while the "risks for serious harms related to opioid therapy increase at higher opioid dosage." The CDC specifically explains that "there is now an established body of scientific evidence showing that overdose risk is increased at higher opioid dosages." The CDC also states that there is an "increased risk[] for opioid use disorder, respiratory depression, and death at higher dosages." As a result, the CDC advises doctors to "avoid increasing dosage" above 90 morphine milligram equivalents per day. These findings contradict statements made by Defendants that increasing dosage is safe and that under-treatment is the cause for certain patients' aberrant behavior.

173. The 2016 CDC Guideline also contradicts statements made by the Defendants that there are reliable risk-mitigation tactics to reduce the risk of addiction. For instance, the Guideline indicates that available risk screening tools "show insufficient accuracy for classification of patients as at low or high risk for [opioid] abuse or misuse" and counsels that doctors "should not overestimate the ability of these tools to rule out risks from long-term opioid therapy."

174. Finally, the 2016 CDC Guideline states that "[n]o studies" support the notion that "abuse-deterrent technologies [are] a risk mitigation strategy for deterring or preventing abuse," noting that the technologies—even when they work—"do not prevent opioid abuse through oral intake, the most common route of opioid abuse, and can still be abused by non-oral routes." In particular, the CDC found as follows:

> The "abuse-deterrent" label does not indicate that there is no risk for abuse. No studies were found in the clinical evidence review assessing the effectiveness of abuse-deterrent technologies as a risk mitigation strategy for deterring or preventing abuse. In addition, abuse-deterrent technologies do not prevent unintentional overdose through oral intake. Experts agreed that recommendations could not be offered at this time related to use of abuse-deterrent formulations.

Accordingly, the CDC's findings regarding "abuse-deterrent technologies" directly contradict Purdue and Endo's claims that their new pills deter or prevent abuse.

175. In addition, as discussed above, in contrast to Defendants' statements that the 1980 NEJM letter provided evidence of the low risk of opioid addiction in patients treated for pain, the NEJM recently published a letter largely debunking the use of the 1980 letter as evidence for such a claim.[89] The researchers demonstrated how the 1980 letter was irresponsibly cited and, in some cases, "grossly misrepresented," when in fact it did not provide evidence supporting the broad claim of low addiction risk for all patients prescribed opioids for pain. As noted above, the 1980 letter's authors reviewed only files of patients administered opioids in a hospital setting, rather than patients sent home with a prescription for opioids to treat chronic pain.

176. The authors of the 2017 letter described their methodology as follows:

> We performed a bibliometric analysis of this [1980] correspondence from its publication until March 30, 2017. For each citation, two reviewers independently evaluated the portrayal of the article's conclusions, using an adaptation of an established taxonomy of citation behavior along with other aspects of

[89] Pamela T.M. Leung, B.Sc. Pharm., Erin M. Macdonald, M.Sc., Matthew B. Stanbrook, M.D., Ph.D., Irfan Al Dhalla, M.D., David N. Juurlink, M.D., Ph.D., *A 1980 Letter on the Risk of Opioid Addiction*, 376 N Engl J Med 2194-95 (June 1, 2017), http://www.nejm.org/doi/full/10.1056/NEJMc1700150#t=article.

> generalizability . . . For context, we also ascertained the number of citations of other stand-alone letters that were published in nine contemporaneous issues of the Journal (in the index issue and in the four issues that preceded and followed it).
>
> We identified 608 citations of the index publication and noted a sizable increase after the introduction of OxyContin (a long-acting formulation of oxycodone) in 1995 ... Of the articles that included a reference to the 1980 letter, the authors of 439 (72.2%) cited it as evidence that addiction was rare in patients treated with opioids. Of the 608 articles, the authors of 491 articles (80.8%) did not note that the patients who were described in the letter were hospitalized at the time they received the prescription, whereas some authors grossly misrepresented the conclusions of the letter ... Of note, affirmational citations have become much less common in recent years. In contrast to the 1980 correspondence, 11 stand-alone letters that were published contemporaneously by the Journal were cited a median of 11 times.[90]

177. The researchers provided examples of quotes from articles citing the 1980 letter, and noted several shortcomings and inaccuracies with the quotations. For instance, the researchers concluded that these quotations (i) "overstate[] conclusions of the index publication" (ii) "do[] not accurately specify its study population," and (iii) did not adequately address "[l]imitizations to generalizability."[91]

178. Based on this review, the researchers concluded as follows:

> [W]e found that a five-sentence letter published in the Journal in 1980 was heavily and uncritically cited as evidence that addiction was rare with long-term opioid therapy. We believe that this citation pattern contributed to the North American opioid crisis by helping to shape a narrative that allayed prescribers' concerns about the risk of addiction associated with long-term opioid therapy. In 2007, the manufacturer of OxyContin and three senior executives pleaded guilty to federal criminal charges that they misled regulators, doctors, and patients about the risk of addiction associated with the drug. Our findings highlight the potential consequences of inaccurate citation and underscore the need for diligence when citing previously published studies.[92]

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[90] *Id.* (emphasis added).

[91] Supplementary Appendix to Pamela T.M. Leung, B.Sc. Pharm., Erin M. Macdonald, M.Sc., Matthew B. Stanbrook, M.D., Ph.D., Irfan Al Dhalla, M.D., David N. Juurlink, M.D., Ph.D., *A 1980 Letter on the Risk of Opioid Addiction*, 376 N Engl J Med 2194-95 (June 1, 2017), http://www.nejm.org/doi/suppl/10.1056/NEJMc1700150/suppl_file/nejmc1700150_appendix.pdf

[92] Pamela T.M. Leung, B.Sc. Pharm., Erin M. Macdonald, M.Sc., Matthew B. Stanbrook, M.D., Ph.D., Irfan Al Dhalla, M.D., David N. Juurlink, M.D., Ph.D., *A 1980 Letter on the Risk of Opioid Addiction*, 376 N Engl J Med 2194-95 (June 1, 2017), http://www.nejm.org/doi/full/10.1056/NEJMc1700150#t=article.

179. These researchers' careful analysis demonstrates the falsity of Defendants' claim that this 1980 letter was evidence of a low risk of addiction in opioid-treated patients. By casting this letter as evidence of low risk of addiction, Defendants played fast and loose with the truth, with blatant disregard for the consequences of their misrepresentations.

D. Defendants have reaped unprecedented profits from the sale of opioids.

180. Defendants have reaped enormous profits from the addiction crisis they spawned. In 2014 alone, opioids generated $11 billion in revenue for pharmaceutical drug companies like Defendants.

181. In fact, Purdue has generated estimated sales of more than $35 billion from opioids since 1996, while raking in more than $3 billion in 2015 alone. Purdue is 100% privately owned by a single family, the Sacklers, whose net worth was $14 billion as of 2015. All nine members of the Purdue board are family members, and all of the company's profits go to Sackler family trusts and entities.[93]

182. Purdue's annual opioid sales of $3 billion in 2015 represent a four-fold increase from its 2006 sales of $800 million.

183. Endo has also profited massively from the sale of opioids. Opioids accounted for more than $400 million of Endo's overall revenues of $3 billion in 2012, and Opana ER alone generated more than $1 billion in revenue for Endo in 2010 and again in 2013.

184. Janssen also generates substantial sales from its opioids. For example, Duragesic accounted for more than $1 billion in sales in 2009, and Nucynta and Nucynta ER accounted for $172 million in sales in 2014.

[93] David Armstrong, *The man at the center of the secret OxyContin files*, Stat News (May 12, 2016), https://www.statnews.com/2016/05/12/man-center-secret-oxycontin-files/.

C. The Role of Wholesale Distributors in the Opioid Crises

185. Pharmaceutical distributors are supposed to play the role of "beat cops" in preventing the flow of controlled substances to abusers.

186. Congress enacted the Controlled Substances Act ("CSA") in 1970 with the express purpose of creating a "closed system" for the distribution of controlled substances designed to prevent the diversion of legally produced controlled substances into illicit markets.[94] Through the CSA, Congress stripped the manufacturers of the ability to sell directly to retailers, intentionally creating a link in the chain of distribution between Big Pharma and the pharmacies. This link is the wholesale distributor.

187. There are only 800 registered wholesale distributors in the United States.

188. Because the CSA creates a "closed system" in which opioid dispensers – like pharmacies – must obtain opioids from opioid distributors, these distributors are "uniquely situated" to spot red flags in the opioid chain, as they note in their own industry guidelines. The distributors are the first line of defense against the diversion of these drugs that can lead to abuse, addiction, and blight.

189. The closed chain of distribution under the CSA is designed to ensure that all controlled substances are accounted for as they make their way from the manufacturer to the end user. As would be expected, all who encounter controlled substances within the distribution chain are required to keep meticulous records. For example, pursuant to 21 C.F.R. § 1305.13(d) distributors of controlled substances must forward a copy of every order filled to the DEA.

1. The Distributor Defendants Are Required to Monitor for and Report Suspicious Orders of Opioids.

[94] *See* 21 U.S.C. §§ 801-971 (2006); 21 U.S.C. §§ 1300-1321 (2009); H.R. Rep. No. 91-1444; 1970 U.S.C.C.A.N. 4566, 4572 (Sept. 10, 1970).

190. Distributors are legally required to be on alert for suspicious controlled substance orders by pharmacies – such as orders of unusual size, frequency or pattern – and to report these unusual orders to the relevant authorities so that they can be investigated.

191. By distributing opioids while failing to monitor for and report suspicious orders, wholesale distributors violated state and federal law. Federal law charges registered wholesale distributors with the non-delegable duty to "design and operate a system to disclose . . . suspicious orders of controlled substances. The registrant [distributor] shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency." 21 C.F.R. § 1301.74(b).

192. Florida law mirrors the requirements promulgated in federal law. Opioids are a Schedule II controlled substance and considered to have a "have potential for abuse…[that]may lead to severe psychological or physical dependence" under Florida law. Fla. Stat. §893.03(c)(2). Florida law also specifically incorporates federal requirements for wholesale drug distributors. Fla. Stat. §893.06.

2. The Distributor Defendants Acknowledge Their Obligations.

193. The distributors have been on specific notice of their duties with regard to suspicious orders since at least September 2006, when the DEA sent distributors letters referencing the federal CSA monitoring and reporting requirements and providing guidance on what may constitute a "suspicious order." These letters identified diversion and abuse of controlled prescription drugs as a "serious and growing health problem," commanded that "distributors must be vigilant" in determining who can be trusted to receive controlled substances, reminded

distributors of their obligation to identify and report suspicious orders, and provided guidance one what circumstances may be indicative of diversion.

194. Unfortunately, rather than conforming their practices to legal requirements, the distributors embarked upon a decade-long pattern of flouting their anti-diversion obligations, requiring repeated DEA action. The United States Department of Justice, Office of the Inspector General, Evaluation and Inspections Divisions, reported that the DEA issued final decisions in 178 registrant actions between 2008 and 2012. The Office of Administrative Law Judges issued a recommended decision in a total of 177 registrant actions before the DEA issued its final decision, including 76 actions involving orders to show cause and 41 actions involving immediate suspension orders.[95] These actions implicated drug diversions and unlawful distributions throughout the country, including in Florida.

195. Among the several DEA enforcement actions, on December 5, 2007, the DEA suspended the license to distribute controlled substances held by Cardinal Health's Lakeland, Florida distribution center, among other Cardinal distribution centers.[96] On December 23, 2016, Cardinal entered into settlement agreements with the United States and paid the United States $44 million to settle claims it had violated the Controlled Substances Act in three states, including Florida.[97]

196. The wholesale distributors have readily admitted their monitoring and reporting obligations. The major pharmaceutical distributors (the potential defendants here) are members of the Healthcare Distribution Alliance ("HDA") (known until mid-2016 as the Healthcare

[95] *The Drug Enforcement Administration's Adjudication of Registrant Actions*, United States Department of Justice, Office of the Inspector General, Evaluation and Inspections Divisions, I2014-003 (May 2014).
[96] *See* Cardinal Health, Inc.'s S.E.C. Form 10-Q for the Quarter Ended December 31, 2008.
[97] *See* https://www.justice.gov/usao-md/pr/cardinal-health-agrees-44-million-settlement-alleged-violations-controlled-substances-act

Distribution Management Association, or "HDMA"), a trade association that represents pharmaceutical distributors throughout the Americas. Such members include, for example, McKesson, and Cardinal Health, the heads of which also sit on the HDA executive committee and board. This membership is significant because, in response to DEA requirements that distributors investigate and report any suspicious controlled substance orders, HDA created "Industry Compliance Guidelines" for pharmaceutical distributors. These Guidelines, which were developed with the "strong endorsement and expertise of [HDA] members" not only function as admissions of the member distributors' duties, but also serve to set out the industry standards to which these distributors may be held.

197. The distributors created these Guidelines "in recognition of a growing problem of misuse and diversion of controlled substances," so that the distributors could "further scrutinize purchase orders for these products," as they were required to do by law. As noted above, the distributors admit that they "are uniquely situated to perform due diligence in order to help support the security" of controlled substance distribution.[98]

199. The Guidelines set out "Know Your Customer Due Diligence" standards with respect to all distributor customers – which, in the context of the Guidelines, comprise pharmacies and other legal dispensaries. These due diligence standards include gathering detailed information on the customer base of a pharmacy, the quantity of prescriptions filled each day, the quantity of controlled substance prescriptions filled each day, and the percentage of controlled substance purchases compared to overall purchases, and then utilizing this information to compare orders to a "threshold" profile to identify orders of unusual size, frequency or pattern. When confronted with "unusual" orders, the distributors' own Guidelines dictate that they should stop the shipments,

[98] *See* HDMA Industry Compliance Guidelines.

investigate the orders under steps that are listed in the Guidelines, and report the suspicious activity to the DEA. These industry standards clearly establish that the duty of care for pharmaceutical distributors includes identifying, investigating, and reporting suspicious orders of controlled substances.

200. Distributors have chosen to abandon their duties, thereby enabling the diversion of opioids and helping to create the present epidemic. The distributors have not performed adequate due diligence and have failed to report suspicious orders, breaching the very industry standards they, themselves, created. In doing so, the distributors have violated their duties of care and both federal and Florida state law.

3. The Distributors Defendants Have Misrepresented Material Facts.

201. In addition to the publicly available evidence of the distributors' ongoing troubles with the DEA, the distributors are on record fraudulently reassuring the public that they were complying with their obligations under the CSA. For example, a Cardinal Health executive claimed that it uses "advanced analytics" to monitor its supply chain, and assured the public it was being "as effective and efficient as possible in constantly monitoring, identifying, and eliminating any outside criminal activity."[99] Given the sales volumes and the company's history of violations, this executive was either untruthful, or Cardinal Health had such a system, but it ignored the results.

202. Similarly, McKesson publicly stated that it has a "best-in-class controlled substance monitoring program to help identify suspicious orders," and claimed it is "deeply passionate about

[99] https://www.washingtonpost.com/investigations/how-drugs-intended-for-patients-ended-up-inthe-hands-of-illegal-users-no-one-was-doing-their-job/2016/10/22/10e79396-30a7-11e6-8ff7b6c1998b7a0_story.html?utm_term=.744e85035bdc

curbing the opioid epidemic in our country."[100] Again, given McKesson's historical conduct, this statement is either false, or the company ignored outputs of the monitoring program.

4. "ARCOS" Data Contains Key Evidence of the Distributors Defendants' Breaches.

203. One of the ways wholesale distributors are supposed to maintain controls against the diversion of prescription opiates is by inputting all distributions in the DEA Automation of Reports and Consolidated Orders System (ARCOS) database.[101] This database contains monthly reports from each wholesale distributor and documents the number of doses of each controlled substance sold to every pharmacy on a monthly basis.

204. The wholesale distributors were required to monitor this data for suspicious orders. When "suspicious orders" were identified based on this regularly reported data, the wholesale distributors were required to halt shipment, perform an on-site investigation, determine whether a risk of diversion is present, and, if so, report directly to the relevant authorities, including the DEA. "Suspicious orders" are defined by guidance letters provided by the DEA as well as corporate policies and industrial practices, and federal law, which further define the term. For instance, any pharmacy order which exceeds 10% of the prior month's order would be considered a "suspicious order."[102]

205. The information in the ARCOS database is confidential. The public has never seen the data related to the volume of prescription opiates distributed in each community. That changed when a journalist from the Charleston Gazette gained access to records sealed in a lawsuit filed by

[100] https://www.washingtonpost.com/investigations/key-officials-switch-sides-from-dea-topharmaceutical-industry/2016/12/22/55d2e938-c07b-11e6-b527949c5893595e_story.html?utm_term=.68a58d17478e

[101] *See United States v. Four Hundred Sixty Three Thousand Four Hundred Ninety Seven Dollars & Seventy Two Cents ($463,497.72) in U.S. Currency From Best Bank Account*, 779 F. Supp. 2d 696, 709 (E.D. Mich. 2011).

[102] *See Southwood Pharmaceuticals, Inc.*, 72 FR 36487 (2007); *Cardinal Health, Inc. v. Holder*, 846 F. Supp. 2d 203 (D.D.C. 2012).

the West Virginia Attorney General against the wholesale distributors. The data revealed that 780 million prescription opiates were distributed in West Virginia (population 1.8 million) during a six-year window of time. The journalist, Eric Eyre, recently won the Pulitzer Prize for his investigative journalism.

206. Florida has the ability through local law enforcement and cooperation with the DEA to seek and obtain historical ARCOS data. Because this information contains a record of every order filled by each pharmaceutical distributor, a review of those orders would allow for a determination of how many suspicious orders were not flagged by the distributors.

207. The absence of real-time monitoring and reporting by the distributors stripped Florida and the DEA of their ability to timely identify, investigate, and prevent the diversion of the highly addictive opioid drugs.

E. The BHME's have been significantly harmed as a result of Defendants' conduct.

208. As a result of Defendants' misrepresentations and deceptive statements about prescription opioids, the BHME's have suffered significant and ongoing damages in multiple ways, including but not limited to increased health care costs, increased human services costs, costs related to dealing with opioid-related crimes and emergencies, and other public safety costs.

V. CLAIMS FOR RELIEF

COUNT ONE
VIOLATIONS OF FLORIDA'S DECEPTIVE AND UNFAIR TRADE PRACTICES ACT, FLA. STAT. § 501.201, *ET SEQ*.

209. Plaintiff repeats, reasserts, and incorporates the allegations contained above as if fully set forth herein.

210. Defendants have violated and continue to violate Florida's Deceptive and Unfair Trade Practices Act, Fla. Stat. § 501.201, *et seq*. ("FDUTPA") because they engaged in

unconscionable commercial practices, deception, fraud, false pretense, false promise, misrepresentation, or the knowing concealment, suppression, or omission of a material fact or facts in connection with the sale, distribution, or advertisement of merchandise as alleged herein.

211. These unfair methods of competition and unfair and/or deceptive acts or unconscionable practices in the conduct of trade or commerce were reasonably calculated to deceive the BHME's and its consumers, and did in fact deceive the BHME's and its consumers. Each Defendant's misrepresentations, concealments, and omissions continue to this day.

212. Specifically, misrepresentations and false claims include, but are not limited to:

a. Defendants' marketing and public claims and statements that the risks of long-term opioid use and the risk of addiction were overblown;

b. Defendants' claims that opioid doses can or should be increased until pain relief is achieved;

c. Defendants' claims that evidence supports the long-term use of opioids for chronic pain;

d. Defendants' claims that chronic opioid therapy would improve patients' function and quality of life;

e. Defendants' misrepresentations regarding the signs of addiction;

f. Defendants' claims that screening tools effectively prevent addiction;

g. Defendants' failures to monitor and report opioid use and potential for misuse as required by law;

h. Defendants' claims that abuse-deterrent opioids reduce tampering and abuse; and

i. Claims that Defendants cooperate with and support efforts to prevent opioid abuse and diversion.

213. Defendants also omitted to state material facts that they had a duty to disclose by virtue of Defendants' other representations and applicable law, with the intent that others rely on their omissions or suppression of information, including but not limited to, failing to disclose that:

a. opioids are highly addictive and may result in overdose or death;

b. the use of screening tools as a strategy for reducing abuse or diversion are not effective;

c. high dose opioids subject the user to greater risks of addiction, other injury, or death;

d. the risks of hyperalgesia, hormonal dysfunction, decline in immune function, mental clouding, confusion, and dizziness, increased falls and fractures in the elderly, neonatal abstinence syndrome, and potentially fatal interactions with alcohol or benzodiazepines;

e. the benefits of chronic opioid therapy lacked scientific support or were contrary to the scientific evidence;

f. opioids fails to last a full twelve hours in many patients;

g. abuse-deterrent formulations are not designed to address, and have no effect on, the most common route of abuse (oral abuse), can be defeated with relative ease; and may increase overall abuse; and

h. then were aware of suspicious prescribers.

214. Defendants' statements about the use of opioids to treat chronic pain were not supported by, or were contrary to, the scientific evidence, as confirmed by the CDC and FDA.

215. Further, Defendants' omissions, which were false and misleading in their own right, rendered even seemingly truthful statements about opioids false and misleading and likely to mislead.

216. Defendants' acts and practices regarding prescribers and consumers as alleged in this Complaint are unconscionable commercial practices and are immoral, unethical, and offensive to established public policy, including:

217. Defendants' acts and practices as alleged constituted unfair competition. At all times relevant to this Complaint, Defendants promoted opioids as superior to competing products, such as NSAIDs, and exaggerated the risks of NSAIDs while ignoring risks of adverse effects of opioids.

218. The BHME's is part of the broad class of persons that may avail themselves of a remedy under FDUTPA.

219. The BHME's have been injured as a direct and proximate result of Defendants' violations of the Consumer Fraud Act as alleged in this Complaint.

220. The BHME's have suffered ascertainable loss of money or property as a result of Defendants acts and practices alleged in this Complaint.

221. Defendants are liable for three times The BHME's's actual damages and reasonable attorneys' fees, filing fees, and reasonable costs of suit. The Court should also grant injunctive relief enjoining Defendants from future violations of the CPA. Defendants' actions, as complained of herein, constitute unfair competition or unfair, deceptive or fraudulent acts or practices in violation of the CPA.

COUNT TWO
PUBLIC NUISANCE

222. Plaintiffs repeat, reassert, and incorporate the allegations contained above as if fully set forth herein.

223. A public nuisance is one which affects equally the rights of an entire community, although the extent of the damage may be unequal.

224. In addition, a public nuisance constitutes an unreasonable interference with a right common to the general public, such as a condition dangerous to health, offensive to community moral standards, or unlawfully obstructing the public in the free use of public property.

225. The BHME's and the patients they serve have a right to be free from conduct that endangers their health and safety. Yet Defendants have engaged in conduct which endangers or injures the health and safety of the BHME's and their patients by their production, promotion,

marketing of opioids for use by patients of the BHME's and by their failure to monitor, report and prevent such abuses.

226. Each Defendant has created or assisted in the creation of a condition that is injurious to the health and safety of the BHME's and their patients, and interferes with the comfortable enjoyment of life and property of entire communities and/or neighborhoods.

227. Defendants' conduct has caused deaths, serious injuries, and a severe disruption of the public peace, order and safety, including fueling the homeless and heroin crises facing the BHME's described herein. Defendants' conduct is ongoing and continues to produce permanent and long-lasting damage.

228. The health and safety of the patients of the BHME's, including those who use, have used, or will use opioids, as well as those affected by users of opioids, are matters of substantial public interest and of legitimate concern to the BHME's patients.

229. Defendants' conduct has impacted and continues to impact a substantial number of people within the BHME's service areas and is likely to continue causing significant harm to patients with chronic pain who are being prescribed and take opioids, their families, and their communities.

230. But for Defendants' actions, there is no doubt that opioid use and ultimately its misuse and abuse would not be as widespread as it is today, and the massive epidemic of opioid abuse that currently exists would have been averted.

231. Logic, common sense, justice, policy, and precedent indicate Defendants' unfair and deceptive conduct has caused the damage and harm complained of herein. Defendants knew or reasonably should have known that their statements regarding the risks and benefits of opioids were false and misleading, and that their false and misleading statements and failures to monitor

and curb and prevent abuse were causing harm. Thus, the public nuisance caused by Defendants to the BHME's was reasonably foreseeable, including the financial and economic losses incurred by the BHME's.

232. Defendants' actions were, at the very least, a substantial factor in opioids becoming widely available and widely used, in deceiving healthcare professionals and patients about the risks and benefits of opioids for the treatment of chronic pain, and in the public health crisis that followed.

233. Defendants knew or should have known that their promotion of opioids was false and misleading and that their deceptive marketing scheme and other unlawful, unfair, and fraudulent actions would create or assist in the creation of a public nuisance.

234. Defendants' conduct in creating and maintaining the public nuisance were neither fully regulated nor required by any federal or Florida law, and in fact were contrary to public policy and guidance from the FDA and CDC.

235. The public nuisance alleged herein can be abated and further recurrence of such harm and inconvenience can be abated.

236. The BHME's have been, and continue to be, directly and proximately injured by Defendants' actions in creating a public nuisance.

237. Florida statutory law contemplates that the BHME's are among the entities that may pursue redress for behavioral health nuisances created in the counties they serve. The BHME's suffered special injuries distinguishable from those suffered by the general public.

238. Defendants' conduct was accompanied by wanton and willful disregard of persons who foreseeably might be harmed by their acts and omissions.

COUNT THREE
NEGLIGENCE

239. Plaintiffs repeat, reassert, and incorporate the allegations contained above as if fully set forth herein.

240. Each Defendant owed a duty of care to the BHME's and their residents, including but not limited to taking reasonable steps to prevent the misuse, abuse, and over-prescription of opioids.

241. In violation of this duty, Defendants failed to take reasonable steps to prevent the misuse, abuse, and over-prescription of opioids in the counties the BHME's serve by misrepresenting the risks and benefits associated with opioids.

242. As set forth above, Defendants' misrepresentations include falsely claiming that the risk of opioid addiction was low, falsely instructing doctors and patients that prescribing more opioids was appropriate when patients presented symptoms of addiction, falsely claiming that risk-mitigation strategies could safely address concerns about addiction, falsely claiming that doctors and patients could increase opioid usage indefinitely without added risk, deceptively marketing that purported abuse-deterrent technology could curb misuse and addiction, and falsely claiming that long-term opioid use could actually restore function and improve a patient's quality of life. Each of these misrepresentations made by Defendants violated the duty of care to the BHME's and the residents of the counties they serve.

243. As a direct and proximate cause of Defendants' unreasonable and negligent conduct, the BHME's and the residents of the counties they serve have suffered and will continue to suffer harm, and are entitled to damages in an amount determined at trial.

244. Additionally, as a direct and proximate result of Defendants' negligence, the BHME's have been directly harmed in that Defendants' conduct has rendered them unable to fully

meet the needs of the communities they serve without performing extra services for which they have not been compensated.

COUNT FOUR
VIOLATIONS OF THE RACKETEER INFLUENCED AND CORRUPT ORGANIZATIONS ACT, 18 U.S.C. § 1961, ET SEQ.

245. Plaintiffs hereby incorporate by reference the allegations contained in the preceding paragraphs of this complaint.

246. This claim is brought by the BHME's against each Defendant for actual damages, treble damages, and equitable relief under 18 U.S.C. § 1964 for violations of 18 U.S.C. § 1961, et seq.

247. At all relevant times, each Defendant is and has been a "person" within the meaning of 18 U.S.C. § 1961 (3), because they are capable of holding, and do hold, "a legal or beneficial interest in property."

248. Each of the BHME's is a "person," as that term is defined in 18 U.S.C. § 1961(3), and has standing to sue as it was and is injured in its business and/or property as a result of the Defendants' wrongful conduct described herein.

249. Section 1962(c) makes it "unlawful for any person employed by or associated with any enterprise engaged in, or the activities of which affect, interstate or foreign commerce, to conduct or participate, directly or indirectly, in the conduct of such enterprise's affairs through a pattern of racketeering activity ..." 18 U.S.C. § 1962(c).

250. Section 1962(d) makes it unlawful for "any person to conspire to violate" Section 1962(c), among other provisions, fee 18 U.S.C. § 1962(d).

251. Each Defendant conducted the affairs of an enterprise through a pattern of racketeering activity, in violation of 18 U.S.C. § 1962(c) and § 1962(d).

A. Description of the Defendants' Enterprise.

251. RICO defines an enterprise as "any individual, partnership, corporation, association, or other legal entity, and any union or group of individuals associated in fact although not a legal entity." 18 U.S.C. § 1961(4).

252. Under 18 U.S.C. § 1961(4) a RICO "enterprise" may be an association-in-fact that, although it has no formal legal structure, has (i) a common purpose, (ii) relationships among those associated with the enterprise, and (iii) longevity sufficient to pursue the enterprise's purpose. See Boyle v. United States, 556 U.S. 938, 946 (2009).

253. Defendants formed such an association-in-fact enterprise—referred to herein as "the Enterprise."

254. Defendants' illegal scheme was hatched by an association-in-fact enterprise between the Manufacturer Defendants and the Distributor Defendants.

255. The Enterprise is an ongoing and continuing business organization consisting of "persons" within the meaning of 18 U.S.C. § 1961(3) that created and maintained systematic links for a common purpose: to sell drugs, specifically opioids, that have little or no demonstrated efficacy for the pain they are purported to treat in the majority of persons that obtain prescriptions for them. The additional sales of opioids attributable to the conspiracy enumerated to the financial benefit of all the Defendants, unifying their common purpose in violating the laws that were designed to protect against the very abuse at the heart of the epidemic.

256. To accomplish this purpose, the Enterprise engaged in a sophisticated, well-developed, and fraudulent marketing scheme designed to increase the prescription rate for the Manufacturer Defendants' opioid medications and popularize the misunderstanding that the risk of addiction to prescription opioids is low when used to treat chronic pain (the "Scheme").

B. The Enterprise sought to fraudulently increase Defendants' profits and revenues.

257. At all relevant times, each Manufacturer Defendant was aware of the conduct of the Enterprise, was a knowing and willing participant in that conduct, and reaped profits from that conduct in the form of increased sales and prescriptions of their opioid medications while the Distributor Defendants received payments from the Manufacturer Defendants in exchange their role in the Enterprise, and to advance the Enterprise's fraudulent marketing scheme.

258. The Enterprise functioned by selling prescription opioids. While there are some legitimate uses and/or needs for prescription opioids, these RICO Defendants, through their illegal enterprise, engaged in a pattern of racketeering activity, that involves a fraudulent scheme to increase revenue by violating State and Federal laws requiring the maintenance of effective controls against diversion of prescription opioids, and the identification, investigation, and reporting of suspicious orders of prescription opioids.

259. The goal of Defendants' scheme was to increase profits from opioid sales. But, Defendants' profits were limited by the production quotas set by the DEA, so the Defendants refused to identify, investigate and/or report suspicious orders of their prescription opioids being diverted into the illicit drug market. The end result of this strategy was to increase and maintain artificially high sales of opioids.

260. The Enterprise engaged in, and its activities affected, interstate and foreign commerce because it involved commercial activities across states lines, such as t h e manufacture, sale, distribution, and shipment of prescription opioids throughout the country and this jurisdiction, and the corresponding payment and/or receipt of money from these activities.

261. Within the Enterprise, there were interpersonal relationships and common communication by which these Defendants shared information on a regular basis.

262. One example of this communication and organization is illustrated by the role of the HDA which, as alleged above, led to the formation of interpersonal relationships and an organization between these RICO Defendants. The HDA website confirms that the Distributor Defendants and the Manufacturer Defendants named in the Complaint, including Actavis (*i.e.*, Allergan), Endo, Purdue, Mallinckrodt and Cephalon were members of the HDA. And the HDA and the Distributor Defendants, sought the active membership and participation of the Manufacturer Defendants by advocating that one of the benefits of membership included the ability to develop direct relationships between Manufacturers and Distributors at the executive levels.

263. In fact, the HDA actively touted the benefits of membership to the Manufacturer Defendants, advocating that membership would provide the ability to, among other things, "network one on one with manufacturer executives at HDA's members-only Business and Leadership Conference," "networking with HDA wholesale distributor members," "opportunities to host and sponsor HDA Board of Directors events," "participate on HDA committees, task forces and working groups with peers and trading partners," and "make connections." Clearly, the HDA was part of the coordination in fact of the Enterprise.

264. These RICO Defendants also maintained their interpersonal relationships by working together and exchanging information and driving the unlawful sales of their opioids through their contractual relationships, including chargebacks and vault security programs.

265. The Manufacturer Defendants engaged in an industry-wide practice of paying rebates and/or chargebacks to the Distributor Defendants for sales of prescription opioids. More

specifically, there is an industry-wide practice whereby the Manufacturers paid the Distributors rebates and/or chargebacks on their prescription opioid sales.

266. On information and belief, these contracts were negotiated at the highest levels, demonstrating ongoing relationships between the Manufacturer and Distributor Defendants. In return for the rebates and chargebacks, the Distributor Defendants provided the Manufacturer Defendants with detailed information regarding their prescription opioid sales, including purchase orders, acknowledgements, ship notices, and invoices. The Manufacturer Defendants used this information to gather high-level data regarding overall distribution and direct the Distributor Defendants on how to most effectively sell the prescription opioids.

267. The contractual relationships among the RICO Defendants also include vault security programs. The RICO Defendants are required to maintain certain security protocols and storage facilities for the manufacture and distribution of their opiates. Plaintiffs are informed and believe that manufacturers negotiated agreements whereby the Manufacturers installed security vaults for Distributors in exchange for agreements to maintain minimum sales performance thresholds. These agreements were used by the RICO Defendants as a tool to violate their reporting and diversion duties in order to increase their overall sales of opioids.

268. Taken together, the interaction and length of the relationships between and among the Manufacturer and Distributor Defendants reflects a deep level of interaction and cooperation between two groups in a tightly knit industry. The Manufacturer and Distributor Defendants were not two separate groups operating in isolation or two groups forced to work together in a closed system. The RICO Defendants operated together as a united entity, working together on multiple fronts, to engage in the unlawful sale of prescription opioids. The HDA and the Pain Care Forum are but two examples of the overlapping relationships, and concerted joint efforts to accomplish

common goals and demonstrates that the leaders of each of the RICO Defendants was in communication and cooperation.

269. During the time period alleged in this Complaint, the RICO Defendants exerted control over, conducted and/or participated in the Opioid Diversion Enterprise by fraudulently failing to comply with their Federal and State obligations to identify, investigate and report suspicious orders of opioids in order to prevent diversion of those highly addictive substances into the illicit market, to halt such unlawful sales and, in doing so, to increase production quotas and generate unlawful profits.

270. For example, the Defendants pattern of activity included at least the following:

- disseminated false and misleading statements to the public claiming that they were in compliance with their obligations to maintain effective controls against diversion of their prescription opioids.
- disseminated false and misleading statements to the public claiming that they were complying with their obligations to design and operate a system to disclose to the registrant suspicious orders of their prescription opioids.
- disseminated false and misleading statements to the public claiming that they were complying with their obligation to notify the DEA of any suspicious orders or diversion of their prescription opioids.
- paid nearly $800 million dollars to influence local, state and federal governments through joint lobbying efforts as part of the Pain Care Forum. The RICO Defendants were all members of their Pain Care Forum either directly or indirectly through the HDA. The lobbying efforts of the Pain Care Forum and its members, included efforts to pass legislation making it more difficult for the DEA to suspend and/or revoke the Manufacturers' and Distributors' registrations for failure to report suspicious orders of opioids.
- exercised control and influence over the distribution industry by participating and maintaining membership in the HDA.
- Applied political and other pressure on the DOJ and DEA to halt prosecutions for failure to report suspicious orders of prescription opioids and lobbied Congress to strip the DEA of its ability to immediately suspend registrations pending investigation by passing the "Ensuring Patient Access and Effective Drug Enforcement Act."

271. The Enterprise engaged in, and its activities affected, interstate and foreign commerce because it involved commercial activities across state boundaries, including but not limited to: (1)

the marketing, promotion, and advertisement of Defendants' opioid drugs; (2) the advocacy at the state and federal level for change in the law governing the use and prescription of Defendants' opioid drugs; (3) the issuance of prescriptions and prescription guidelines for Defendants' opioid drugs; and (4) the issuance of fees, bills, and statements demanding payment for prescriptions of Defendants' opioid drugs.

C. Predicate acts: mail and wire fraud

272. To carry out, or attempt to carry out, the scheme to defraud, the members of the Enterprise, each of whom is a person associated-in-fact with the Enterprise, did knowingly conduct or participate, directly or indirectly, in the affairs of the Enterprise through a pattern of racketeering activity within the meaning of 18 U.S.C. §§ 1961 (1), 1961 (5) and 1962(c), and employed the use of the mail and wire facilities, in violation of 18 U.S.C. § 1341 (mail fraud) and § 1343 (wire fraud).

273. Specifically, the members of the Enterprise have committed, conspired to commit, and/or aided and abetted in the commission of, at least two predicate acts of racketeering activity (i.e., violations of 18 U.S.C. §§ 1341 and 1343), within the past ten years.

274. The multiple acts of racketeering activity which the members of the Enterprise committed, or aided or abetted in the commission of, were related to each other, posed a threat of continued racketeering activity, and therefore constitute a "pattern of racketeering activity."

275. The racketeering activity was made possible by the Enterprise's regular use of the facilities, services, distribution channels, and employees of the Enterprise.

276. The members of the Enterprise participated in the Scheme by using mail, telephone, and the internet to transmit mailings and wires in interstate or foreign commerce.

277. The members of the Enterprise used, directed the use of, and/or caused to be used, thousands of interstate mail and wire communications in service of their Scheme through common misrepresentations, concealments, and material omissions.

278. In devising and executing the illegal Scheme, the members of the Enterprise devised and knowingly carried out a material scheme and/or artifice to defraud Plaintiffs and the public to obtain money by means of materially false or fraudulent pretenses, representations, promises, or omissions of material facts.

279. For the purpose of executing the illegal Scheme, the members of the Enterprise committed these racketeering acts, which number in the thousands, intentionally and knowingly with the specific intent to advance the illegal Scheme.

280. The Enterprise's predicate acts of racketeering (18 U.S.C. § 1961(1)) include, but are not limited to:

> Mail Fraud: The members of the Enterprise violated 18 U.S.C. § 1341 by sending or receiving, or by causing to be sent and/or received, fraudulent materials via U.S. mail or commercial interstate carriers for the purpose of selling drugs, specifically opioids, that have little or no demonstrated efficacy for the pain they are purported to treat in the majority of persons prescribed them.
>
> Wire Fraud: The members of the Enterprise violated 18 U.S.C. § 1343 by transmitting and/or receiving, or by causing to be transmitted and/or received, fraudulent materials by wire for the purpose of selling drugs, specifically opioids, that have little or no demonstrated efficacy for the pain they are purported to treat in the majority of persons prescribed them.

281. The RICO Defendants' use of the mail and wires includes, but is not limited to, the transmission, delivery, or shipment of the following by the Manufacturers, Distributors, or third parties that were foreseeably caused to be sent as a result of the RICO Defendants' illegal scheme, including but not limited to: The prescription opioids themselves; Documents and communications that facilitated the manufacture, purchase and unlawful sale of prescription opioids; Defendants'

DEA registrations; Documents and communications that supported and/or facilitated Defendants' DEA registrations; Documents and communications that supported and/or facilitated the Defendants' request for higher aggregate production quotas, individual production quotas, and procurement quotas; Defendants' records and reports that were required to be submitted to the DEA pursuant to 21 U.S.C. § 827; Documents and communications related to the Defendants' mandatory DEA reports pursuant to 21 U.S.C. § 823 and 21 C.F.R. § 1301.74; Documents intended to facilitate the manufacture and distribution of Defendants' prescription opioids, including bills of lading, invoices, shipping records, reports and correspondence; Documents for processing and receiving payment for prescription opioids; Payments from the Distributors to the Manufacturers; Rebates and chargebacks from the Manufacturers to the Distributors; Payments to Defendants' lobbyists; Payments to Defendants' trade organizations, like the HDA, for memberships and/or sponsorships; Deposits of proceeds from Defendants' manufacture and distribution of prescription opioids; and other documents and things, including electronic communications.

282. Many of the precise dates of the fraudulent uses of the U.S. mail and interstate wire facilities have been deliberately hidden, and cannot be alleged without access to Defendants' books and records. However, Plaintiffs have described the types of predicate acts of mail and/or wire fraud, including certain specific fraudulent statements and specific dates upon which, through the mail and wires, Defendants engaged in fraudulent activity in furtherance of the Scheme.

283. The members of the Enterprise have not undertaken the practices described herein in isolation, but as part of a common scheme and conspiracy. In violation of 18 U.S.C. § 1962(d), the members of the Enterprise conspired to violate 18 U.S.C. § 1962(c), as described herein. Various other persons, firms, and corporations, including third-party entities and individuals not named as defendants in this Complaint, have participated as co-conspirators with Defendants and

the members of the Enterprise in these offenses and have performed acts in furtherance of the conspiracy to increase or maintain revenue, increase market share, and/or minimize losses for the Defendants and their named and unnamed co-conspirators throughout the illegal scheme and common course of conduct.

284. The members of the Enterprise aided and abetted others in the violations of the above laws.

285. To achieve their common goals, the members of the Enterprise hid from Plaintiffs and the public: (1) the fraudulent nature of Defendants' marketing scheme; (2) the fraudulent nature of statements made by Defendants and on behalf of Defendants regarding the efficacy of and risk of addiction associated with Defendants' opioid medications; and (3) the true nature of the relationship between the members of the Enterprise.

286. Defendants and each member of the Enterprise, with knowledge and intent, agreed to the overall objectives of the Scheme and participated in the common course of conduct. Indeed, for the conspiracy to succeed, each of the members of the Enterprise and their coconspirators had to agree to conceal their fraudulent scheme.

287. The members of the Enterprise knew, and intended that, Plaintiffs and the public would rely on the material misrepresentations and omissions made by them and suffer damages and a result.

288. As described herein, the members of the Enterprise engaged in a pattern of related and continuous predicate acts for years. The predicate acts constituted a variety of unlawful activities, each conducted with the common purpose of obtaining significant monies and revenues from Plaintiffs and the public based on their misrepresentations and omissions.

289. The predicate acts also had the same or similar results, participants, victims, and methods of commission.

290. The predicate acts were related and not isolated events.

291. The true purposes of Defendants' Scheme were necessarily revealed to each member of the Enterprise. Nevertheless, the members of the Enterprise continued to disseminate misrepresentations regarding the nature of Defendants' opioid medications and the functioning of the Scheme.

292. Defendants' fraudulent concealment was material to Plaintiffs and the public. Had the members of the Enterprise disclosed the true nature of the Defendants' opioid medications, The BHME's would not have acted as it did, including relying on Defendants' misrepresentations to its detriment.

293. The pattern of racketeering activity described above is currently ongoing and open-ended, and threatens to continue indefinitely unless this Court enjoins the racketeering activity.

D. The BHME's have been damaged by Defendants' RICO violations.

294. By reason of, and as a result of the conduct of the Enterprise and, in particular, its pattern of racketeering activity, the BHME's have been injured in their business and/or property in multiple ways, including but not limited to increased health care costs, increased human services costs, costs related to dealing with opioid-related family and child protection issues, and other costs, as fully described above.

295. Defendants' violations of 18 U.S.C. § 1962(c) and (d) have directly and proximately caused injuries and damages to The BHME's and the public who are entitled to bring this action for three times its actual damages, as well as injunctive/equitable relief, costs, and reasonable attorney's fees pursuant to 18 U.S.C. § 1964(c).

PRAYER FOR RELIEF

WHEREFORE, the BHME's respectfully requests the Court order the following relief:

A. An Order that the conduct alleged herein constitutes violations of the Florida Deceptive and Unfair Trade Practices Act;

B. An Order that the conduct alleged herein constitutes a public nuisance under Florida law;

C. An Order that Defendants abate the public nuisance that they caused under Florida law;

D. An Order that Defendants are negligent under Florida law;

E. An Order that Defendants have been unjustly enriched at Plaintiffs expense;

F. An Order that Defendants' conduct constitutes violations of the Racketeer Influenced and Corrupt Organizations Act ("RICO"), 18 U.S.C. §1961, el seq.;

G. An Order that Plaintiffs are entitled to treble damages pursuant to RICO;

I. An Order that Plaintiffs are entitled to recover all measure of damages permissible under the statutes identified herein and under common law;

J. An Order that judgment be entered against Defendants in favor of Plaintiffs;

K. An Order that Plaintiffs are entitled to attorney's fees and costs pursuant to any applicable provision of law, including but not limited to under the Florida Deceptive and Unfair Trade Practices Act and RICO; and

L. An Order awarding any other and further relief deemed just and proper, including pre-judgment and post-judgment interest on the above amounts.

M. An Order granting the BHME's equitable relief to include (1) enjoining Defendants from continuing the conduct described herein; (2) requiring Defendants to disgorge themselves of the ill-gotten profits from the sale of opioids; and (3) requiring Defendants to create a fund from which the BHME's will address the ongoing fallout from the opioid epidemic in the counties they serve.

JURY TRIAL DEMAND

Plaintiffs demand a trial by jury on all claims and of all issues so triable.

Dated: April 4, 2018

/s/ Oscar M. Price, IV

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